Center for Food Regulation and Research

ELECTRONIC REGISTRATION

USER BOOKLET

FOREWORD

Application of all processed food products, through the electronic registration system, is an offshoot of the electronic registration of raw materials and low risk food products which started way back in December 2014. Following its release, an improved version of the system – intended to cover all submissions to the Center for Food Regulation & Research (CFRR), was developed alongside other enhancements, which were incorporated in the current system, for faster transactions and submissions, and ultimately, for a more efficient delivery of public service.

A glance through the pages of this booklet will show the reader the current system and different authorizations issued by the center which consists of the process flow, frequently asked questions (FAQs) and list of references. All efforts have been exhausted by the CFRR to consolidate these application process flow and FAQs in order to simplify this booklet. Stakeholders and readers alike will find this booklet a useful quick guide in their applications as it provides a road map of how they should go about their submissions. It cites examples or scenarios that applicants will encounter in the course of their transaction with the FDA. Moreover, it is a compendium of resources or references the stakeholders could use when familiarizing with FDA processes, policies and regulations.

Overall, this booklet aims to provide a simplified guidance to existing stakeholders/clients and new applicants as it is designed to address the issues and concerns regarding different food applications, quick process flow guide – of all CFRR-issued authorizations, and the things to be expected from those engaged in the processed food business.

With its publication, I hope that this electronic registration user booklet will bridge the gap between the FDA-CFRR and its stakeholders.

NELA CHARADE G. PUNO, RPh
Director General
Food and Drug Administration

INTRODUCTION

INTRODUCTION

This booklet has been prepared by the Food and Drug Administration – Center for Food Regulation Research (CFRR) and is intended to be used as a quick guide and reference for process information to minimize error during filling and securing of Certificate of Product Registration (CPR) and other authorization.

The User Booklet is the mini version of the CFRR Registration User Manual which contains specific processes in order to understand the Electronic Registration System. This booklet does not only focus on the CPR Application but also includes specific processes and frequently asked questions on different authorization issued by the Center.

GENERAL GUIDELINES IN THE REGISTRATION OF FOOD PRODUCTS

1. Requirements for registration are based on the requirements indicated in Administrative Order 2014-0029 and FDA Circular 2016-014:

   A. Proof of payment or fees as prescribed by current FDA regulations;

   B. Clear and complete loose labels or artworks, as applicable, of all packaging size, or equivalents as defined by FDA regulations except of bulk raw materials, ingredients and food additives intended for further processing or for distribution to establishments/manufacturers for further processing;

   C. Pictures of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered, as applicable;

   D. For food supplement, a sample in actual commercial presentation shall be submitted.

   E. For food products with label claims: as applicable, documents to substantiate claims, such as technical, nutritional or health studies or reports, market research studies, Certificate of Analysis, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification to support use of logo/seal on Sangkap Pinoy, halal, Organic, or Kosher food and in compliance with current labelling regulations.

   F. Additional requirements for food supplement are the following:

      *Certificate of Analysis for physico-chemical and microbiological parameters

      *Shelf life study with stability data containing relevant information on the critical parameters of the finished product, period conducted, conclusion, and signed/verified by competent technical staff to support shelf life declaration.

      *Safety data (Acute Oral Toxicity Test (LD-50 Test, Heavy Metals Test, other cytoxicity tests, safe history of use or other tests to assess potential toxicity as applicable)

2. All food additives must conform with the Updated List of Food Additives and/or latest General Standard for Food Additives based on Bureau Circular 2006-016 and Administrative Order 2014-0029. Food flavours must be listed in Flavors and Extracts Manufacturers Association (FEMA) or International

Organization of the Flavor Industry (IOFI) Generally Recognized As Safe Lists based on B.C. 2006-016 or latest FDA Regulation on Food Additives.

3. Based on FDA Circular 2016-007, **additional requirements for imported products include** ANY of the following scanned copy of the original documents:

   (1) Foreign Agency Agreement or (2) Certificate of Distributorship or (3) Appointment letter or (4) Proforma Invoice or (5) Memorandum of Agreement from the supplier.

   AND ANY of the following documents issued by the Regulatory/ Health Authority/Internationally Recognized Certifying Body:

   (1) Certificate of Registration with GMP Compliance or its equivalent or (2) Valid Sanitary Phyto-Sanitary Certificate or (3) Health Certificate or (4) ISO 22000 Certificate or (5) FSSC Certificate or (6) HACCP Certificate or (7) Certificate of Free Sale issued to the Manufacturer.

   In case, the Certificate of Free Sale is issued by the Chamber of Commerce or trade association, this should be duly authenticated by the Philippine Consulate from the country of origin.

4. Food products with standards of identity should conform with the specification in the corresponding standards thru submission of Certificate of Analysis.

5. Medium and high risk food products should conform with the microbiological parameters as indicated in FDA Circular 2013-010.

6. Processed food products containing food additives with restricted levels (e.g. nitrite in meat products) should not exceed the maximum levels allowed in the Updated List of Food Additives (B. C. 2006-016) or FDA latest Regulation on Food Additives. A Certificate of Analysis on the level of such restricted food additive in the finished product must be submitted.

7. Thermally processed food products packed in hermetically sealed containers (e.g. can, bottle) should submit Tests Results for Commercial Sterility.

8. Labels of food products applying for registration should conform to the current labelling guidelines based on Administrative Order 2014-0030.

GENERAL GUIDELINES IN THE REGISTRATION OF FOOD PRODUCTS

The mandatory labelling requirements are:

- Brand name
- Product name
- List of ingredients including common name and function of food additives
- Net weight
- Complete name and address of manufacturer, packer, distributor, trader or importer. For imported products, country of origin should be declared.
- Nutrition labelling (nutrition facts)
- Expiration date/use by date/consume before date
- Lot identification code
- Allergen information as applicable
- Storage instruction/Instruction for use as applicable.
- % alcohol for alcoholic beverages only
- Country of origin (for imported products only)
- English translation if Foreign language is used
- Additional labelling requirements for food supplements: Mandatory declaration of "Food Supplement" and NO APPROVED THERAPEUTIC CLAIMS based on Bureau Circular 2 s. 1999 (bold, Arial, font size 14 and all capital letters).

Food products for export should conform with the labelling requirements of the importing country.

- Additional labelling requirements apply to specific products with standards of identity or Philippine National Standards.
- Additional precaution/caution statements are declared on the label.

If labels of processed food products bear any health and nutrition claims, these should comply with the Guidelines for Health and Nutrition Claims based on the Codex Guidelines on Health and Nutrition Claims for Use in Food as adopted thru Bureau Circular 2007-002.

9. For food products requiring the use of salt as an ingredient, it is mandatory to use iodized salt for local food products intended for local distribution based on Republic Act 8172 (ASIN Law).

10. The following staple food products should be fortified with Vitamin A and/or

iron-based on Republic Act 8976 and must submit the Certificate of Analysis and compliant label as additional requirements in the registration:

*Cooking Oil-Vitamin A

*Wheat Flour-Iron and Vitamin A

*Sugar-Vitamin A

*Rice-Vitamin A

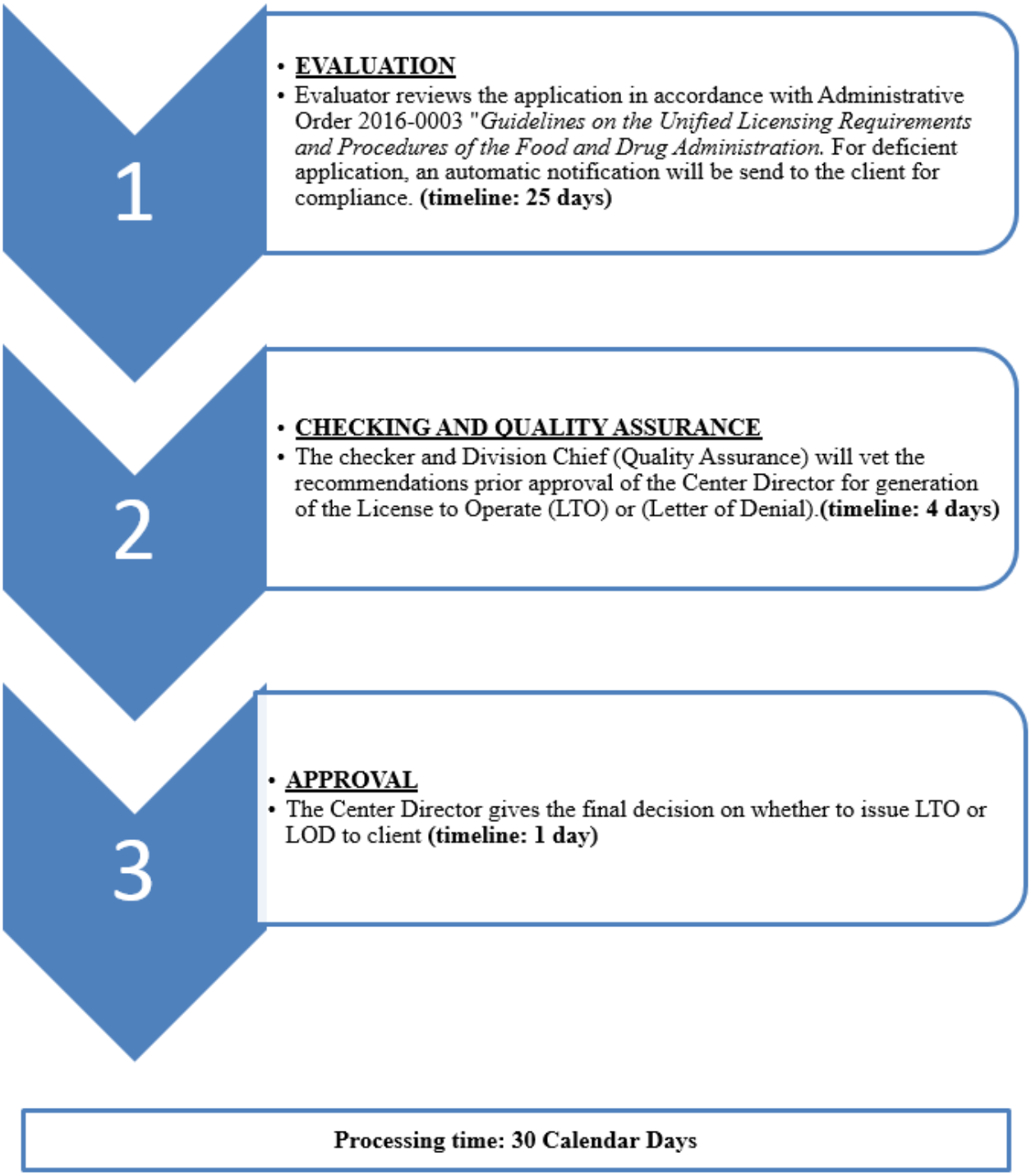
11. Voluntary fortification of processed food products must conform with AO 04 s. 1995.

12. The following high risk food products should conform with the corresponding Codex Standards:

- Infant Formula: Codex Standard for Formula for Special Medical Purposes Intended for Infants and Infant Formula (Codex STAN 72-1981 Rev. 2006)
- Follow up Formula or Milk Supplement: Codex Standard for Follow Up Formula (Codex STAN 156-1987)
- Cereal-based Foods for Older Infants and Young Children: Codex Standard for Processed Cereal-based Foods for Older Infants and Young Children (Codex STAN 074-1981 Revised 2006)
- Formulated Complementary Foods for Infants and Young Children (Codex GL-9-1991 Revised 2013)
- Canned Baby Foods: Codex Standard for Canned Baby Foods (Codex STAN 73-1981)
- Foods for Special Medical Purposes: Codex Guidelines for the Labeling and Claims of Foods for Special Medical Purposes (Codex STAN 180-1991)
- Foods for Special Dietary Uses: Codex Standard for the Labeling of Prepackaged Foods for Special Dietary Uses (Codex STAN 146-1985)
- Formula Foods for Weight Control Diets: Codex Standard for Formula Foods for Weight Control Diets)

APPLICATION PROCESS FLOWCHART

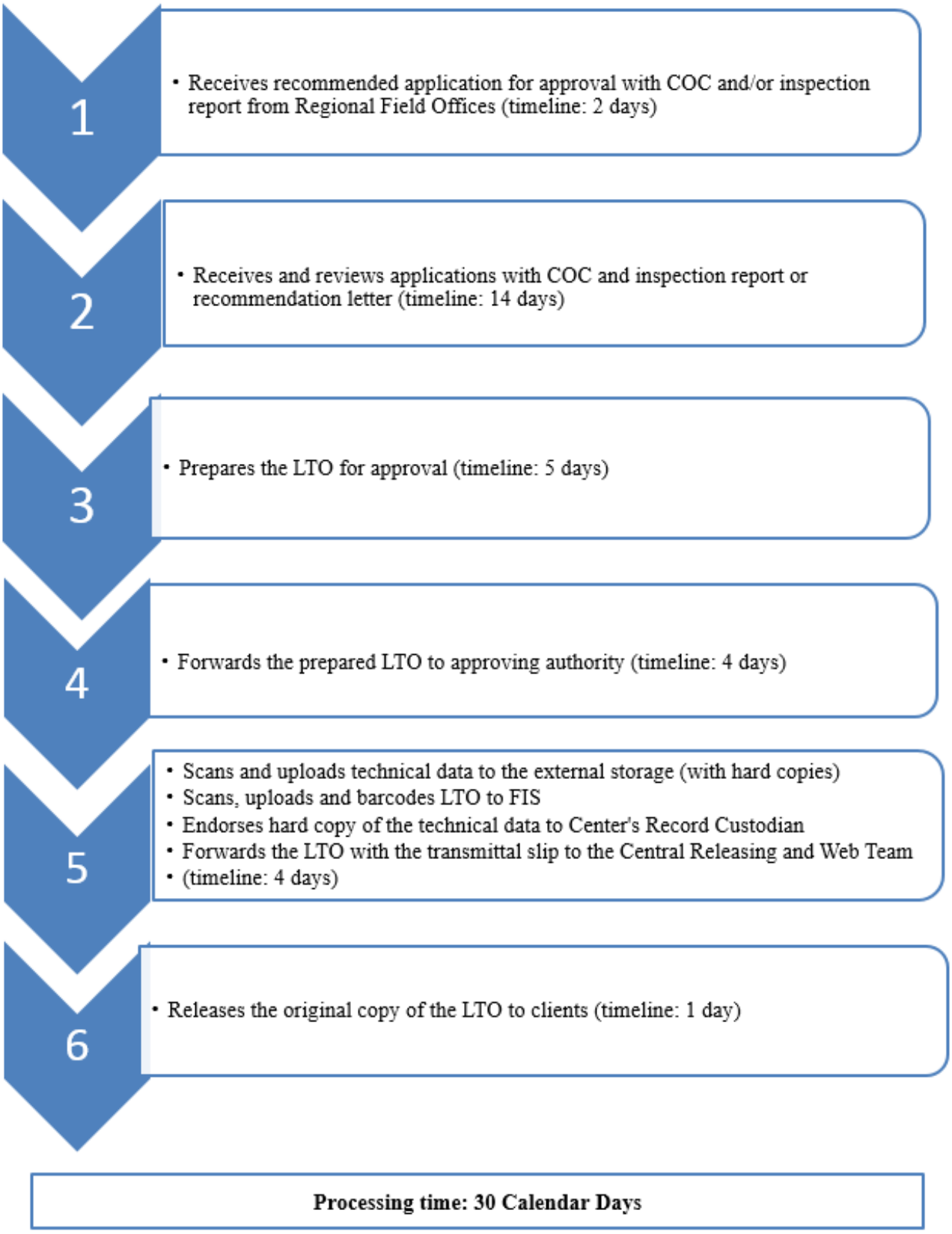
A. LICENSING OF FOOD ESTABLISHMENTS VIA E-LTO



Note: For initial application as Food Manufacturer, the Citizen's Charter timeline for inspection by Regional Field Offices is 60 calendar days.

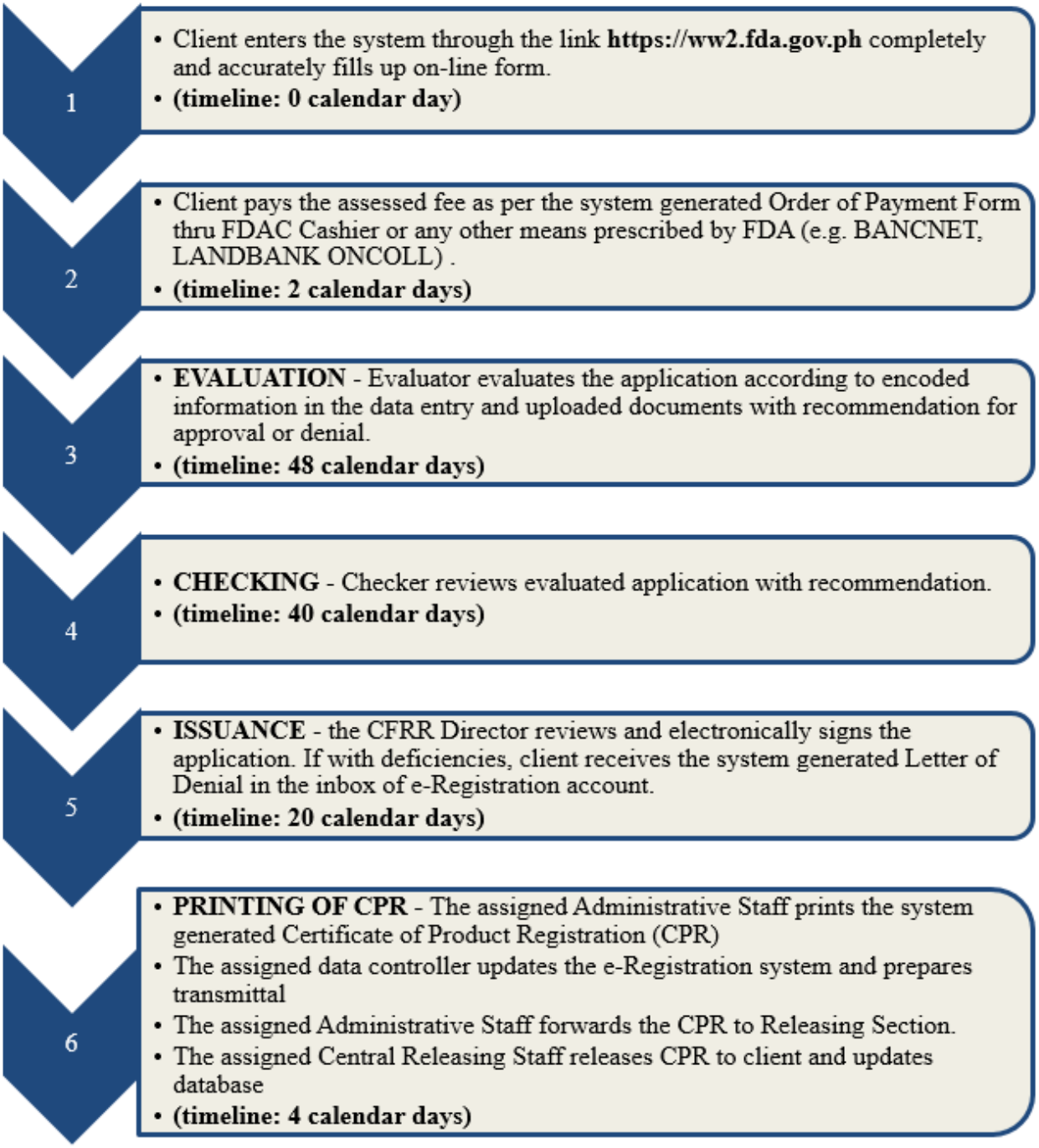
APPLICATION PROCESS FLOWCHART

B. LICENSING OF FOOD ESTABLISHMENTS VIA MANUAL APPLICATION



APPLICATION PROCESS FLOWCHART

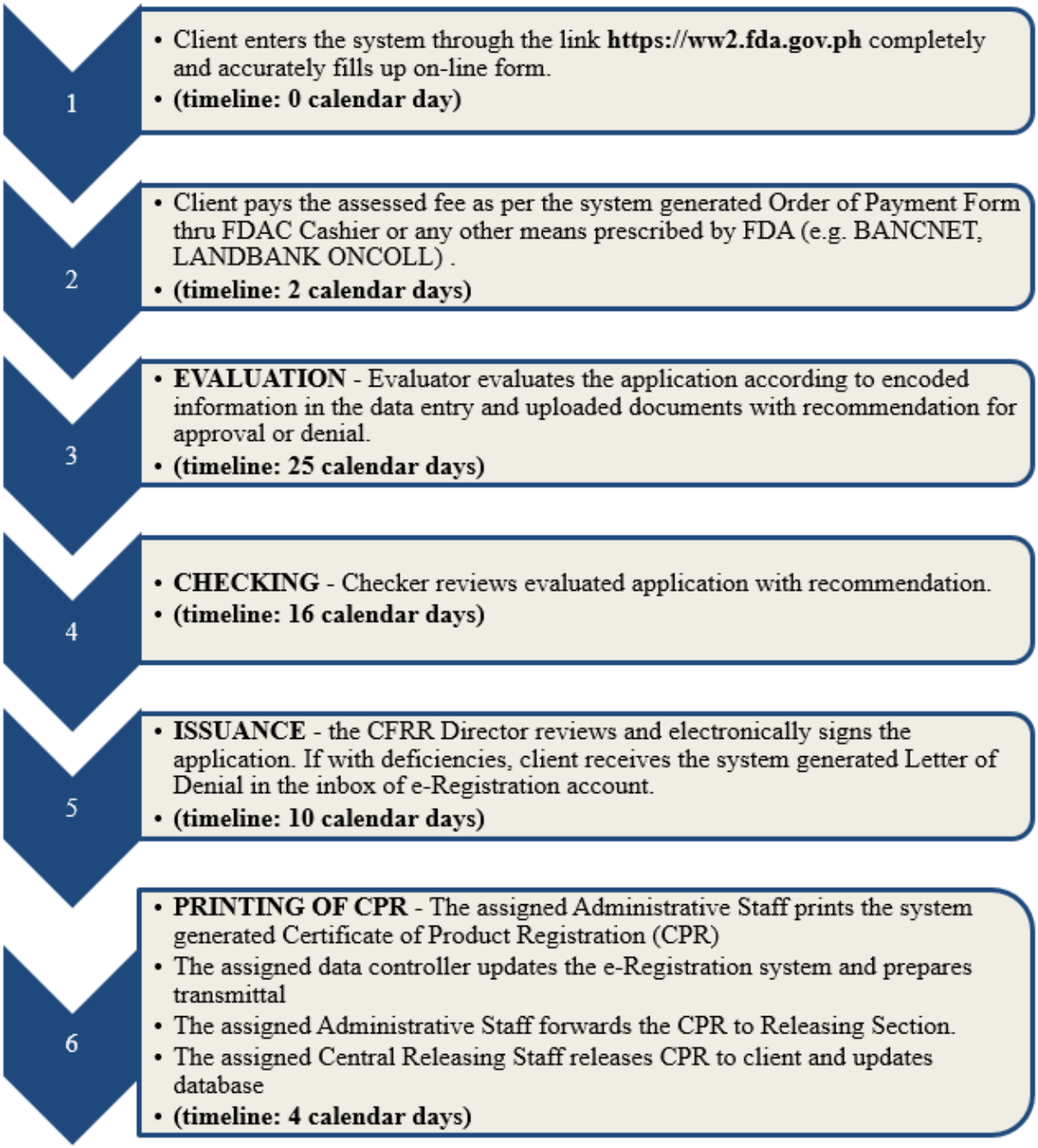
C. REGISTRATION OF PRE-PACKAGED, PROCESSED FOOD PRODUCTS (INITIAL/RENEWAL DATA CAPTURE/AMENDMENT DATA CAPTURE/REAPPLICATION DATA CAPTURE) VIA E-REGISTRATION



Total CPR e-Registration System Processing time: **114 Calendar Days**

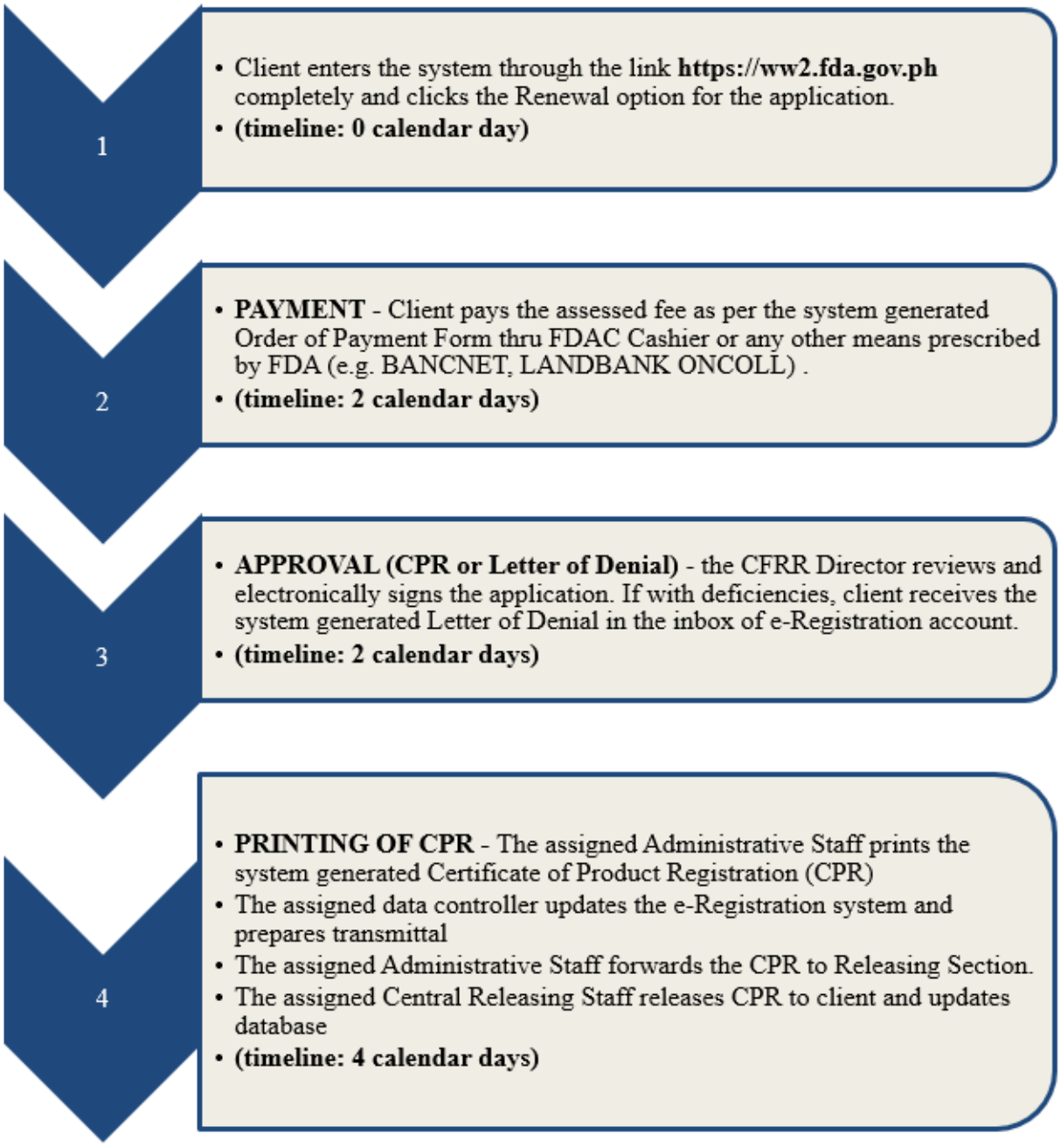
APPLICATION PROCESS FLOWCHART

D. REGISTRATION OF PRE-PACKAGED, PROCESSED FOOD PRODUCTS FOR EXPORT/REAPPLICATION (INITIAL APPLICATION DENIED VIA E-REGISTRATION/AMENDMENT (INITIALLY APPROVED VIA E-REGISTRATION) VIA E-REGISTRATION



Total CPR e-Registration System Processing time (Export/Reapplication (Initial Application denied via E-Registration/Amendment (Initially approved via E-Registration)):
57 Calendar Days

E. CPR AUTOMATIC RENEWAL APPLICATION INITIALLY APPROVED FROM E-REGISTRATION



Total CPR e-Registration System Processing time (**CPR Automatic Renewal Application initially approved from e-Registration**): **7 Calendar Days**

APPLICATION PROCESS FLOWCHART

F. ISSUANCE OF BOC CLEARANCE

1

- Client submits the hard copy of the documents to PAIR and the assigned personnel shall receive the application and generate the acknowledgement receipt to be forwarded to the client.
- The assigned personnel shall forward the application to Center for Food and Regulation (CFRR).
- The Administrative Staff updates the status of the application as received by the CFRR.
- The Administrative Staff forwards the application to the assigned Food Drug Regulation Officer (FDRO) and updates the document tracking system.
- **(timeline: 1 calendar day)**

2

- **EVALUATION** - The assigned FDRO evaluates the completeness and corectness of the submitted requirements.
- The evaluator shall print the BOC Clearance.
- The Chief reviews evaluated application and affixes his/her signature.
- The CFRR Director reviews and signs the application.
- **(timeline: 2 calendar days)**

3

- **CHECKING** - Checker reviews the printed BOC Clearance or Letter of Denial.
- **(timeline: 1 calendar day)**

4

- **ISSUANCE** - The assigned Administrative Staff ensures that the BOC Clearance has dry seal.
- The assigned Administrative Staff forwards the BOC Clearance to Releasing Unit.
- The assigned Central Releasing Staff releases CPR to client and updates database
- **(timeline: 1 calendar day)**

Total Processing Time: **3 working days**

APPLICATION PROCESS FLOWCHART

G. SALES PROMO PERMIT AND APPLICTATION

1
- Client enters the system through the link **https://ww2.fda.gov.ph** completely and accurately fills up on-line form.
- **(timeline: 0 calendar day)**

2
- Client pays the assessed fee as per the system generated Order of Payment Form thru FDA Main Office Cashier or any other means prescribed by FDA (e.g. BANCNET) .
- **(timeline: 7 calendar days)**

3
- Client submits requirements in soft copy through FDAC during the scheduled day of appearance.
- **(schedule of submission: every Friday)**

4
- **UPDATING OF DATABASE** - Evaluator receives application from FDAC, encodes it to the internal database, prints Document Tracking Log and assigns permit number.
- **(timeline: 3 calendar days)**

5
- **EVALUATION** - Evaluator evaluates the application with recommendation for approval or denial.
- Any clarification will be communicated to the clients through electronic communication or telephone indicating the assigned Document Tracking Number (DTN) (**STOP CLOCK**).
- If with deficiences, violations, or needs to be referred to the Inter-Agency Committee on Milk Code, evaluator drafts Letter of Denial/Endorsement Letter.
- **(timeline: 4 calendar days)**

6
- **CHECKING** - Checker reviews printed permit or Letter of Denial/Endorsement Letter.
- **(timeline: 1 calendar day)**

7
- **QUALITY ASSURANCE** - The LRD Chief reviews and signs the printed permit or Letter of Denial/Endorsement letter
- **(timeline: 1 calendar day)**

7
- **ISSUANCE (Sales Promotion Permit or Letter of Denial/Endorsement Letter)** - the LRD Chief and CFRR Director signs the Sales Promotion Permit or Letter of Denial/Endorsement Letter.
- The assigned Administrative Staff forwards the approved Sales Promotion Permit or Letter of Denial with transmittal to Releasing Unit.
- The assigned Central Releasing Staff endorses the permit or letter to courier service for delivery.
- **(timeline: 1 calendar day)**

Total Sales Promotion Permit Application Processing time:
14 Calendar Days upon receipt from PAIR

FREQUENTLY ASKED QUESTIONS

LICENSING OF FOOD ESTABLISHMENTS

1. What is a License to Operate (LTO)?

>>*LTO is an authorization issued by the FDA to an establishment to grant permission to undertake a trade or carry out a business activity, such as manufacturing, importation, exportation, sale, offering for sale, distribution, or transfer of food products.*

2. Who will apply for License to Operate?

>>*The following food establishments regulated by the FDA shall secure a License to Operate:*

a. *Manufacturers are establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packaging, repacking, altering, ornamenting, finishing and labelling with the end in view of its storage, sale or distribution.*

b. *Repackers are establishment engaged in the process of packaging or changing of container, wrapper (that may include or not a changing of label) from a bulk material to retail packaging sizes in furtherance of distribution of food.*

c. *Toll manufacturers are manufacturer that conduct contract manufacturing where conditions of the contract are defined, agreed and controlled; and all aspects of contracted work are specified to obtain quality product/s conforming to the agreed standards.*

d. *Distributor/Importer/Exporter are establishments that that imports or exports raw materials, ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer.*

e. *Traders are establishment which is a registered owner of food and food products and/or procure the raw materials and packing components, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.*

f. Wholesalers are establishments engaged in local distribution of pre-packaged food products in commercial quantity.

3. How do I apply for License to Operate?

>>Application of License to Operate is through the FDA Electronic Portal. The use of the new application form and the corresponding procedures thru the e-portal facilitates application in terms of timeliness and ease of submission especially for the Applicants outside of the National Capital Region. Please refer to FDA Circular 2016-004. (http://www.fda.gov.ph/attachments/article/330042/FDA%20Circular%20No.%202016-004.pdf)

4. What are the requirements for the application License to Operate? AO 2016-0003

>>The following documents shall be uploaded using the E-Portal. Scanned copy should be 100-150 dpi (dots per inch), maximum of 2MB

Initial/Renewal

1. *For the declared authorized officer in the application form:*
   a. *Board resolution/Board Certificate for Corporation;*
   b. *Power of Attorney for single proprietorship;*
   c. *Partnership resolution for partners and*
   d. *Authority from the head of agency for government agency*
2. *Business Name Registration:*
   a. *For single proprietorship Certificate of Business Registration issued by the Department of Trade and Industry (DTI);*
   b. *For corporation, partnership and other juridical person - Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation;*
   c. *For cooperative - Certificate of Registration issued by the Cooperative Development Authority and Articles of Cooperation; or*
   d. *For government-owned or controlled corporation - the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter.*
3. *Relevant credential/s of the declared qualified person in the application form (e.g. QPIRA certificate for Food/HACCP/Food Safety Seminar Certificate)*

Variation

The list of variations, the conditions, and the documentary requirements is attached as Annex B of AO No. 2016-0003

http://www.fda.gov.ph/attachments/article/328922/AO%20No.%202016-0003.pdf

5. How long is the validity of the LTO?

>>Unless revoked, the LTO shall have the following validity period:

a. An initial license issued shall be valid for two (2) years

b. A renewed license shall be valid for five (5) years while a renewed license for bottled water processor is three (3) years.

6. What is the legal basis for the issuance of LTO?

>>Administrative order 153 s. 2004 (Revised Guidelines on Current Good Manufacturing Practice in Manufacturing, Packing, Repacking or Holding Food), AO 18-a s. 1993 and RA 8172 (ASIN Law)

7. What are the prescribed fees and charges?

Classification	***Initial (2 years validity)***	***Renewal (5 years validity)***
1. Food Distributors (Importer, Exporter, Wholesaler)	*8,000.00*	*20,000.00*
2. Food Manufacturer		
2.1 1M and below	*2,000.00*	*5,000.00*
2.2 over 1M but below 5M	*4,000.00*	*10,000.00*
2.3 5M but below 10M	*6,000.00*	*15,000.00*
2.4 10M but below 20M	*10,000.00*	*25,000.00*
2.5 20M but below 50M	*20,000.00*	*50,000.00*
2.6 50M and above	*30,000.00*	*75,000.00*
3. For Bottled Water follow AO 18-A s. 1993 and RA8172 for iodized salt		

Note: Surcharges/penalties are imposed for late renewal as per FDA Circular 2011-004.

LRF – FDA Circular No. 2011-003 Collection of Legal Research Fee Imposed by RA 3870

8. How do I pay for LTO application?

Step 1: Go to the BancNet Online homepage. (https://www.bancnetonline.com). Select the Banc of your choice.

Step 2: A Security Message pop-up window will appear. Click "Continue" to proceed.

Step 3: Read the terms and conditions then click the "I Agree" button to proceed.

Step 4: Click "Payment" and set "FDA Philippines" as the Biller/Institution in the drop down.

Step 5: Take note of the "Account Number" found in the Order of Payment that will be generated right after filling up the FDA online registration form as this will serve as the "Reference Number". Enter the "Account Number" on the "Reference Number: text box and fill up the other information needed then click submit.

Step 6: Enter the Card Number found in the front of your debit card in the "ATM Card Number" text box. Select "Account type". Enter the "Total Amount Due" in the "Amount to be paid" text box plus the Php 15.00 bank charge.

Step 7: Print the transaction receipt as your payment reference. Payments will be posted in the FDA system after 4-5 calendar days. FDA will issue an Official Receipt (OR) within 5-10 calendar days after posting. Present your printed transaction receipt upon claim of the FDA OR for verification purposes.

You may refer to FDA Advisory No. 2015-021
http://www.fda.gov.ph/attachments/article/241540/FDA%20Advisory%20No.%202015-021.pdf

9. When is the earliest time to apply for renewal?

>>The LTO shall be renewed within 90 days before its expiration as per FDA Circular No 2016-006. Please refer to FDA Circular 2016-006.
http://www.fda.gov.ph/attachments/article/341763/FDA%20Circular%20No.%202016-006.pdf

10.What information are reflected on the Food LTO?

>>Page 1 shall contain Type of application, Primary activities, Name of Establishment, Name of Owner, LTO Number and Validity and Payment Details.

Page 2 shall contain the additional activities (whenever applicable).

You may refer to FDA Circular 2016-006.

http://www.fda.gov.ph/attachments/article/341763/FDA%20Circular%20No.%202016-006.pdf

11.How long is the processing of LTO?

>>30 calendar days upon receipt of complete documents.

FREQUENTLY ASKED QUESTIONS

REGISTRATION OF PRE-PACKAGED, PROCESSED FOOD PRODUCTS (ISSUANCE OF CERTIFICATE OF PRODUCT REGISTRATION)

1. What are the products that need to secure Certificate of Product Registration in the Philippines?

>>*All processed food and food products including food additives, food supplements and bottled water manufactured and/or distributed (i.e. imported, exported and/or wholesale for local distribution), for trade and/or repacked are required to secure a Certificate of Product Registration before these are sold, offered for sale or use, distributed or supplied, among other marketing and promotional activities as per R.A. 9711 and A.O. 2014-0029.*

2. Do I need to secure a CPR for the Raw Materials that I will import for my own use as manufacturer?

>>*Food establishments with License to Operate as Manufacturer and Trader who directly import and use raw materials, ingredients and food additives for their own use or for further processing to manufacture a processed food product, need not secure a CPR for the raw materials, ingredients and food additives. However, the sources of these raw materials should be notified to FDA to be reflected in the Licensing Database of Center for Food Regulation and Research.*

3. What are the requirements to secure a CPR?

>>*You may refer to FDA Circular No. 2016-014 dated 12 August 2016, Procedure for the Use of Electronic (E-Registration) System for Pre-Packaged Processed Food Products prior to filing for registration. For further guidance on registration requirements and food regulations, please refer to AO 2014-0030 (Rules and Regulations on the Licensing of Food Establishments and Registration of Processed Food, and Other Food Products, for Other Purposes). You need to fill up Initial Application Form. You will also need to upload a scanned copy of the following documents in the system during application:*

   a. *Compliant labels in accordance with the prevailing labelling guidelines stipulated in Administrative Order No. 2014-0030*
   b. *Pictures of the product in all angles from at least two different perspectives allowing visual recognition of a product as the same with the one being registered pictures of the product in all angles*
   c. *As applicable, documents to substantiate claims, such as technical, nutritional or health studies or reports, market-research studies, Certificate of Analysis, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or*

certification to support use of logo/seal on Sangkap Pinoy, Halal, Organic, or Kosher food and in compliance with current labelling regulations.

4. How much is the registration fee and how many years is the validity of a CPR?

>>Fees and charges will be computed by the system based on the number of years (2, 3, 4 or 5 years validity) applied for and type of product. You may refer to A.O. 50 s. 2001 for the schedule of fees. Payment may be made through the FDA Cashier by presenting your printed Order of Payment form. Payments through Bancnet Online and Landbank Oncoll are also accepted.

5. Do I need to submit a product sample?

>>Only Initial applications for Food Supplement are required to submit a representative sample in commercial presentation consistent with the E-Registration application. It should be properly labelled with the respective case number, packaged accordingly to protect the contents and submitted to the Food and Drug Administration Main Office Building within ten (10) days upon payment of assessed fee through either of the following means:

a. Personal delivery to the Food and Drug Action Center (FDAC) Unit Starmall Alabang; or
b. Delivery via registered courier with the following information:
- *TO: FOOD AND DRUG ADMINISTRATION – Civic Drive, Filinvest City, Alabang, Muntinlupa City 1781*
- *FROM: Company's complete name and address*
- *SUBJECT: Food Product E-Registration Application (Case No.)*

6. Do I need to file a separate CPR if the product will also be exported?

>>A previously registered product initially for local distribution shall be allowed to be exported using the same CPR as long as the following conditions are met, and labelling and standards of the importing country are likewise met:
a. The same brand name
b. The same product name/variant
c. The same product formulation/ ingredients in the same order of proportion

Amendment application of Packaging Design for export product shall be made and labels in the language of the importing country shall likewise be submitted.

7. How long is the processing time/release of CPR?

>>Applications filed through the E-Registration system are processed within 114 calendar days. You may track the applications through the Process Map function of the system in the electronic portal.

8. Do I still need to secure a CPR even if there is already a CPR issued to other importer/distributor/wholesaler for the same brand name/product?

>>Yes. Each importer should secure his/her own CPR for the products that he/she will import. The name and address of the importer is reflected on the CPR which is needed during importation and release of goods from the Bureau of Customs. The CPR also authorizes the importer/distributor/wholesaler to distribute the products locally.

9. *How do I secure a username and password for E-Registration? Can I use one username and password for all the companies I am handling?*

>>The CFRR E-Registration User Account and Password is company-specific. An authorized representative handling multiple companies must secure a separate user account and password for each respective company. You must secure a notarized authorization letter from the company (with a valid License to Operate Number) being represented or the company account holder. Send the request for a User Account to info@fda.gov.ph following the format specified below with the scanned notarized authorization letter:

SUBJECT: CFRR:E-Registration
BODY: Email Address:
Last Name:
First Name:
Middle Name:
Company Name:

The issued CFRR E-Registration User Account will be sent to the e-mail address you provided in the request. Be sure to check the Spam folder of your e-mail if you have not received a reply within 3 working days.

You may also use your E-LTO User Account and Password for E-Registration by having it validated through a request sent via email to info@fda.gov.ph following this format:

SUBJECT: CFRR:E-Registration (Re-validate)
BODY: Email Address:
Last Name:
First Name:
Middle Name:
Company Name:
User Account:
Password:

The User Account and Password has a validity of 2 years. You will need to renew these by sending a request via email to info@fda.gov.ph following this format:

SUBJECT: CFRR:E-Registration (Renewal of User Account & Password)
BODY: Email Address:
Last Name:
First Name:
Middle Name:
Company Name:
User Account:
Password:

You may refer to FDA Circular 2016-014 for other details and format of documents required in securing a User Account and Password for E-Registration.

10. The cashier cannot view my case number during payment. What should I do?
>>*The application was not forwarded to the cashier. To forward the application, go to the DRAFT section in your e-registration account and click the continue button after generating the Order of Payment Form. If the case number is already in the Participated, the forwarding of payment was successfully made.*

11. Do I need to generate a new Case number for my Amendment/Reapplication if my initial application is already in the E-Registration?
>>*No. This procedure is for Data Capture only wherein it is intended for the applications with existing CPR/Denied during manual procedure (Integrated Application Form). You may view previously approved and denied applications/case numbers in the Inbox of your E-Registration account. Click the specific case number to be amended and choose "Amendment" as type of application.*

In reapplication, click the case number of the denied application in the Inbox and a question "Would you like to reapply" will pop up. Click "yes" and upload the documents/compliance to your denial.

12. How can I use the remaining validity of the CPR of an existing product applied by other company if I will be the new Importer?
>>*(From Manual Registration) this will fall under, Amendment Data Capture, Change in Importer. The new Importer must apply for CPR as amendment and must declare the current FR number and its validity. Attach all the Initial documents and requirements stipulated in AO 2014-0029 Annex D. Please note*

that the existing CPR named under the old Importer must be surrendered upon approval of the amendment.

>>*(From Electronic Registration) this will fall under Amendment Change in Importer. The new Importer must apply for CPR as amendment using own E-registration account and must declare the current FR number and its validity. Attach all the Initial documents and requirements stipulated in AO 2014-0029 Annex D. Please ensure the completeness and correctness of the documents since the old Importer is required to cancel the CPR of the product in their account upon advice of the evaluator by clicking the case number in their inbox and choose "Cancellation" as type of application.*

13. What will be the proof that my applications under Notification of Amendment is approved or disapproved?

>>*Applications under Notification of Amendment will not print a CPR unless it is Amendment Data Capture (The existing CPR is from manual). Once the case number is already in the inbox on your account, you can click the case number and view the Amendment Summary Table which reflects the result of your application. If the application is disapproved, you can see the remarks or reason for its disapproval on the right side of the table.*

14. Where can I categorize my product if it is in conventional form and has herbs, botanicals and other nutritional substances?

>>*There is a new Food Categorization in the system under High Risk HRK2: Herbs and botanicals and/or Products with other nutritional substances and/or combination as Conventional Food Product. This new categorization is not yet specified in the Annex A of FDA Circular No.2016-014 and Administrative Order No.2014-0029 Annex A.*

15. What are the requirements for food supplements?

>>*Same as the requirements for conventional food products as stipulated in the Administrative Order 2014-0029 with the addition of stability study, Certificate of Analysis (COA) of the finished product and as applicable, safety data (e.g. LD-50 Toxicity Test). For food supplements containing herbs which are not listed in any official pharmacopeia and substances with no established safe levels.*

16. What level of Vitamins, Minerals and Herbs are allowed to be registered as a Food Supplement?

>>*Vitamins and Minerals levels are computed by % RENI, as per Office Order 22 s.1991.To be classified as food supplement, the maximum limit is 150% RENI for Water Soluble Vitamins and 105% RENI for Fat Soluble Vitamins. For minerals, PDRI 2015 & ASEAN can be used as reference for the maximum limit. Herbals and Botanicals that cannot be computed since it has no % RENI requires a justification for the safety and test for toxicity study (LD50 Toxicity Test) and/or inclusion in the GRAS list or Official Pharmacopeia Listing.*

17. What should we use as part of the product name: Dietary Supplement or Food Supplement? Is it possible to use Herbal Supplement?

>>*Either Dietary Supplement or Food Supplement is acceptable to use as per the definition of Dietary/Food Supplement on the RA 9711. Herbal Dietary Supplement maybe allowed for food supplement containing multiple herbs but not "Herbal Supplement".*

18. What are the information in the Shelf Life Study?

>>*The Stability Data of the shelf life study should include: conclusion parameters used and methodology declaring the Product name, Batch number, Production date, dates of analysis, Tabulated data & results in terms of physical and chemical and Name and signature of the QA Analyst and QA Manager. We accept results for actual and accelerated shelf life study. If the shelf life study is on-going, results for at least 6 months is allowed.*

19. Do I need to declare the nutrition information in %RENI even if the products are imported vitamins and minerals food supplement?

>>*No, but the levels of Vitamins & Minerals should conform with Office Order 22 s.1991 which sets the limit for vitamins and minerals to be classified as Food Supplement.*

20. For institutional products, a.) If company is owned by a sister company, do we need to apply for CPR? b.) If not company owned, do we need to apply for CPR?

>>*If a product is for institutional use where the "institution" is the sister company which has a separate licensed entity, the product should have a separate CPR.*

If not company owned, either the manufacturer or distributor should register the product.

21. What reference do we use for specifications of raw materials referring to limits for heavy metals?

>>*If the raw material is a specific additive, you may refer to FAO/WHO JECFA for specification on the limits for heavy metals. You may also refer to Food Chemical Codex for specifications of raw materials on limits for heavy metals.*

22. In the absence of CODEX regulations, can we use USFDA or other countries' regulations?

>>*In the absence of national standards, FDA Philippines only uses applicable Codex Alimentarius standards. As per Republic Act 10611 otherwise known as the Food Safety Act of 2013, Codex standards shall be adopted except when these are in conflict with what is necessary to protect consumers and scientific justification exists for action taken.*

23. What will I do to know the status of the application?

>>*Open the case, go to information, and click process map.*

24. I have sent additional documents to info@fda.gov.ph so the evaluator can attach it, but my application was denied.

>>*Sending additional files to info@fda.gov.ph does not guarantee approval of your application unless CFRR has notified you to submit compliance documents. Before sending additional files, be sure that you have received a notification from the concerned evaluator. Also, you must submit the said additional files within the timeline as mentioned in the notification received. Make sure that all attachments are complete before finishing the case/application.*

25. How can we reach the CFRR Registration Section for other inquiries?

>>*You may call us at 857-1900 loc. 8112 or 8115 , or send an email to cfrr_lrd@fda.gov.ph. You may also inquire through our Official Facebook Page https://www.facebook.com/FDAPhilippines/.*

>>*You may also refer to the CFRR Registration User's Manual posted in the FDA Website for the complete and detailed reference in your application for registration.*
https://drive.google.com/file/d/1E_EGhQlulRW0MbeE5HvXvXwpByElDAQF/view

FREQUENTLY ASKED QUESTIONS

LABELLING OF PREPACKAGED FOOD PRODUCTS

1. Can we submit artwork of the label when we apply for product registration?

>>Yes, you can submit artwork or proposed label when you apply for product registration.

2. If my product will be distributed exclusively for export, do I need to comply with the local labeling regulations?

>>No, labels of products exclusive for export market only shall comply with the existing labeling regulations of the importing country or country of destination of the products.

3. If my product is both for local and export market, what labeling regulations will I need to comply for product registration?

>>Labels of products for local distribution should conform to the local labeling regulations (A.O 2014-0030) while the labels for export market should follow the existing labeling regulations of the importing country. You need to print separate label for export market in order to comply with the labeling regulations of the country of destination of your products.

4. Can you approve label without English translation during product registration?

>>No, labels of imported products shall declare the corresponding English translation of mandatory label information. A provisionary sticker can be used for a maximum of six months only. Labels of products in the market should be compliant with the labeling regulations.

5. How many labels do I need to submit in filing product registration?

>>One label for each product should be submitted showing the principal display panel and side panels. A picture of the product showing all angles should be submitted. If your product has different packaging sizes, labels of all different packaging sizes should also be submitted.

6. If the label of my product has changes but I already have Certificate of Product Registration (CPR), how will I seek approval of the revised label?

>>You need to file for amendment of the CPR under label change(s) in the e-portal. You need to upload the ff. requirements: letter requesting for label change, revised label incorporating the changes to be made and amendment fee of PhP 210.00.

7. If the brand name of my product is exactly the same as previously registered, will it be approved?

>>No, you cannot use the brand name of products previously registered with FDA unless you have authorization from the brand name owner.

8. How do we get approval of labels of imported products which are not compliant with the Philippine labeling regulations?

>>If labels of imported products are not compliant with the local labeling regulations, you may opt to print your own labels to be compliant with the FDA regulations.

9. If the label of my product has best before date, will it comply with labeling regulations?

>>No, the label of your product must declare expiry/expiration date or use by date or consume before date in day/month/year format with the name of the month spelled out to be compliant with the labeling regulations.

10. I will register product but with different Store Keeping Unit (SKU) and designs. Do I need to apply for separate CPR for each label design?

>>NO. If the product has multiple SKUs with different design s but with the same formulation, manufacturer, brand name and product name including description you only need to upload all labels of different packaging sizes on your application.

11. Is nature of color is enough to declare in the list of ingredients?

>>No. Color is food additive, therefore common name and nature must be declared on the label.

12. Will FDA allow to use the statement “Made in the Philippines” instead of “Product of the Philippines” which was stated in the Philippine National Standards?

>>Yes.

13. My product is imported; can I apply for CPR with English translation written in a single sticker? If yes, how long can I use the remedial sticker?

>>YES. Stickering is allowed. However, the label information should be printed on, or on a remedial sticker on the label itself and it is only allowed for six months from the date of approval.

14. Is it allowed to declare Recommended Usage of "Take 2 capsules or more daily" for Herb/Botanicals Food Supplements?

>>Yes it is allowed if the main ingredients have no safety issues (Ex. Malunggay, Mangosteen) and it does not contain vitamins exceeding the prescribed limits.

15. Is it allowed to use the statement "Manufactured in USA, Repacked by: ABC PHILS INC." on the label of the product being repacked in the Philippines?
>> *Yes.*

16. Is it allowed to declare "Exclusively Imported by" or "Manufactured for" for imported products manufactured abroad for a local company?
>>*YES. However, the License-to-Operate of the local company must have LTO as Food Importer and that the product is exclusively imported or manufactured for that company.*

17. Is it required to have English Translation on the label of Alcoholic Beverages such as wine, vodka, etc.?
>>*YES. This is in accordance to Administrative Order No. 2014-0030.*

18. Due to global distribution of the imported products, are we allowed to put the name and address of importer in sticker only?
>>*YES. You only need to ensure the durability of the sticker material.*

19. Do Prepacked or repacked foods in grocery in plastic containers (such as sliced fruits, marinated meats such as bbq , etc.) need to follow the labeling requirements?
>>*Yes, as long as it is prepacked.*

20. RENI 2002 is not stated in the A.O 2014-0030. What is the basis that we need to used it for nutritional information?
>>*This is the current RENI adopted by the FDA as per Bureau Circular No. 16 s. 2005*

21. For imported products including Food Supplement without applicable nutrients (based on RENI), is it necessary to follow the Nutrition Information prescribed format indicated in AO 2014-0030?
>>*Yes. However, the corresponding RENI percentage is not mandatory for imported products but all 9 nutrients must be reflected even if it has no value but need to include "0" or "-".*

22. Is it required to include the word "Flavor Added" in close proximity to the photograph of fruits, vegetables, poultry, meat, fish etc. on the label if I only add flavouring substances?
>>*YES.*

FREQUENTLY ASKED QUESTIONS

ISSUANCE OF BOC CLEARANCE

1. How do we secure FDA Clearance (Bureau of Customs Clearance) so that the BOC can release food products intended as samples (i.e. laboratory testing, production trial, research and development) and what are the requirements?

>> *The requesting party needs to submit the hard copy of the following documents to FDAC:*

   a. *Application Letter – addressed to Director Pilar Marilyn M. Pagayunan, this should state the company's reason for importation*
   b. *Affidavit of Undertaking (Original and Notarized) – a statement/clause stating that "the imported products will not be offered for sale or for commercial distribution" or similar statement that the imported products will not reach trade*
   c. *Certificate of Analysis OR Certificate of Free Sale – either of the document is acceptable*
   d. *Commercial or Proforma Invoice*
   e. *Packing List*
   f. *Bill of Lading or Airway Bill – submit if available, however, the request for clearance will still be facilitated even though this is not submitted.*
   g. *Valid LTO – a company without Importer activity may still secure/request BOC clearance*
   h. *Payment (Php 510 per Invoice)*

2. How do we secure FDA Clearance (BOC Clearance) so that the BOC can release food products intended as donation and what are the requirements?

>> *The requesting party should submit the hard copy of the following documents to FDAC:*

   a. *Bureau of International Health Cooperation (BIHC) Endorsement Letter*
   b. *Application Letter or Letter of Intent– addressed to Director Pilar Marilyn M. Pagayunan, this should state the company's reason for importation*
   c. *Certificate of Origin or Certificate of Quality – this should have a statement on the expiration date of the donated products. The expiration date should at least be 12 months uponarrival in the Philippine port.*
   d. *Commercial or Proforma Invoice*
   e. *Packing List*
   f. *Bill of Lading or Airway Bill – submit if available, however, the request for clearance will still be facilitated even though this is not submitted.*
   g. *Payment (Php 510 per Invoice)*
   h. *Letter or Certificate of Donation*
   i. *Deed of Acceptance*

After the clearance is issued to the requesting party, they should contact the Customs Liaison Unit (CLU) for the schedule of inspection. The shipment will not be released without inspection from CLU. Reference: DOH Administrative Order 2016-0004

3. What is the limit or quantity of allowed of imported foods for personal use or personal consumption?

*>>*The Customs Liason Unit of the Regional Field Office – NCR is now handling this type of request.*

The limit is as follows:

a. *Wine – 2 bottles not exceeding 1.5 liters each*
b. *Processed foods – 10 kilograms*
c. *Food supplement – 500 grams*

Reference: BOC and DOH-FDA Joint Circular No. 1 dated 22 June 2015

4. Do we need to amend our CPR if there are changes in alcohol content or vintage?

>>No, you just have to notify the Center for Food Regulation and Research (CFRR) on the product's change in alcohol content and/or vintage.

The following documents should be submitted:

a. *Application Letter/ Letter of Intent – state the changes in the wine*
b. *Affidavit of Undertaking (Original and Notarized) – this should state that the only change in the subject wines are alcohol content and/or vintage*
c. *Label – the submitted label should be the same with the previous label with the exception of alcohol content and/or vintage*

An FDA-CFRR issued letter will be presented to BOC together with the valid CPR to facilitate the release of wines. Reference: FDA Circular 2014-022

5. How do we secure an FDA Export Commodity Clearance?

>>This type of clearance is processed by the FDA Central Laboratory and signed by CSL-Director.

6. Do we need to secure clearance for food products for personal use to be shipped or hand carried outside of the Philippines?

>>Yes. The FDA Central Laboratory is the Office issuing this Certificate or Clearance.

7. How do we secure entry of products for exhibit into the Philippines?
>>You need to submit complete requirements as follows:

a. *Application Letter – addressed to Director Pilar Marilyn M. Pagayunan, this should state the company's reason for importation and the event/exhibit it will partake in*
b. *Affidavit of Undertaking (Original and Notarized) – a statement/clause stating that "the imported products will not be offered for sale or for commercial distribution" or similar statement that the imported products will not reach trade*
c. *Certificate of Analysis OR Certificate of Free Sale – either of the document is acceptable*
d. *Commercial or Proforma Invoice*
e. *Packing List*
f. *Bill of Lading or Airway Bill – submit if available, however, the request for clearance will still be facilitated even though this is not submitted.*
g. *Payment (Php 510 per Invoice)*

8. How do we secure FDA Clearance to join exhibits to be held abroad?
>>The requesting party should have a valid License to Operate to be able to join the exhibit abroad and Payment of Php510.

SALES PROMOTION PERMIT APPLICATION

1. What is the coverage for Sales Promotion of consumer products and services?
>>All promotional campaigns/announcements for consumer products, services, credit facilities which include sponsorships of games shows and similar activities.

2. What are the food products for Sales Promotion covered by FDA?
>>All processed food and food products (complete list is in AO 2014-0029) including:

FOOD Category (Imported & Locally Manufactured)

- *Bakery & Bakery Products*
- *Non-alcoholic beverages & beverages mixes*
- *Candies & confectionary products*
- *Cocoa & Tea and non-dairy creamer*
- *Condiments, sauces and seasoning*
- *Culinary products*
- *Gelatin, Desert preparation & Mixes*
- *Dairy Products*
- *Dressing & spreads*
- *Flour/Flour mixes & Starch*
- *Fish and other marine products*
- *Fruits, vegetable & edible fungi*
- *Meat and poultry products*
- *Noodles, pastas and pastry wrapper*
- *Nut and Nut products*
- *Native delicacies*
- *Oils, fats and shortenings*
- *Snack foods and breakfast cereal*
- *Sugar and other related products*
- *Alcoholic Beverages*
- *Food Supplements*
- *Tea (Herbal)*
- *Bottled Drinking Water*
- *Food for Infant & Children (Growing-up Milk)**
- *Foods for Special Dietary Use*
- *Transgenic food products (use of genetic engineering/biotechnology)*
- *Ethnic food products with indigenous ingredient(s) not common in the Phil.*
- *Dispensed Non-Alcoholic Beverages (for discussion)*

** To be referred to I.A.C–DOH*

>>Marketing and practices covered by the Milk Code shall be forwarded to IAC Secretariat to be deliberated by the IAC on EO 51.
However, only food products duly registered with FDA are allowed to conduct sales promotional activities.

3. What are exempted from the rules on Sales Promotion campaign?
>> a. Government – sponsored Sales promotion campaigns sponsored, when the same is conducted in the exercise of their governmental functions;
b. Social, civic, political, religious, educational, professional and other similar organizations) which extend promotional activity among their members. Provided that the promotional activity is not considered sales promotion campaign as defined under these Rules (per Rules & Regulations Implementing RA 7394).

4. What are the requirements in securing for a Sales Promo Permit?
>>The following requirements in soft copy must be submitted to FDAC:
For Initial Application
a. Integrated Application Form
b. Letter of Intent from the Company of Advertising Agency
c. Accomplished Information Sheet and Mechanics of the Promotion
d. Detailed Mechanics of the Promotion
e. Copy of valid CPR and LTO
f. Advertising/ Collateral Materials to be used in the Promotion
g. Proof of Payment

For Amendment
a. Integrated Application Form
b. Letter of Intent from the Company of Advertising Agency
c. Copy of approved permit
d. Additional Advertising/ Collateral Materials to be used in the Promotion if any
e. Proof of Payment

5. How much is the payment?
>>The fee depends on the coverage of the promotional activity and amount of prizes to be won (per DTI-DOH Joint AO No. 1 s. 2000)

Coverage	*Fee*
NCR only or in several regions in NCR and Nationwide	*Php 1, 010*
More than one (1) region but excluding NCR	*Php 760*
Several provinces/ cities/ municipalities within a single region	*Php 560*
Single province/ city/ municipality	*Php 260*

Amount of Prizes	*Fee*
150,000.00 & below - 300,000.00	*Php 1,010.00*
300,001.00 - 500,000.00	*Php 2,020.00*
500,001.00 - 1,000,000.00	*Php 3,030.00*
Above 1, 000,000.00	Php 5,050.00

For amendment including extension, the fee is Php 310.00, but depends if the amount of prizes will be increased.

6. To which Center should we file our application if the sales promotion will cover combined products of different categories?

Products Involved	Concerned Center
Drugs, Food, Cosmetics, Device, HHS *(or Drug with any categories)*	Center for Drug Regulation and Research (CDRR)
Food, Cosmetics, Device, HHS *(or Device with any product categories excluding Drug)*	Center for Device Regulation, Radiation Health and Research (CDRRHR)
Food, Cosmetics, HHS	Center for Food Regulation and Research (CFRR)
Cosmetics and HHS	Center for Cosmetic Regulation and Research

(Per FDA Memorandum Circular 2013-028)

7. What is the processing period of a sales promo permit application?
>>Processing period is within fourteen (14) calendar days upon receipt from FDAC.

8. When should we apply file the application?
>>At least thirty (30) days before the actual commencement of the sales promotion (per Article 116 of R.A. 7394).

9. What is the general rule on the duration and extension of promotion period?
>>The sales promotion campaign shall have a duration of not more than a year, extendible to a maximum of six (6) months upon approval by the department (per Article 116 of R.A. 7394).

10. What are the General Rules on Advertisements, Promotions, Sponsorship and other Marketing Activities of any health products?
>>As per Book II, Article V of IRR of RA 9711

a. No health product that has not been registered or authorized shall be advertised, promoted or subjected to any marketing activities;

b. *No claim in the advertisement, promotion and sponsorship, and other marketing activities shall be made other than those contained in the approved label or packaging of the health product, or as duly approved by the FDA;*
c. *No claims, therapeutic or scientific otherwise, shall be made that has not been duly approved by the FDA;*
d. *All health products that are permitted to be promoted must specifically state the authority or reference number that approved the same promotional, sponsorship, or marketing activities.*

11. In a price reduction promotions with a period, is the use of the phrase "While supply lasts" allowed?
>>*No. Where such qualification is made in a sales promotion campaign with a period, the sponsor shall be liable therefore throughout the duration of the promotion, whether or not the supply of the products under promotion has been depleted (per Article 116 of R.A. 7394).*

12. How long can a sponsor hold price reduction promotions?
>>Any price reduction promotion on any consumer product or service shall not exceed three (3) months. However, in case of closing – out sales, the period shall be six (6) months *(per Article 116 of R.A. 7394).*

13. How can we follow-up our application?
>>*The status of your application may be checked through the DOCTRACK STATUS function of the FDA website. You may also call us at 857-1900 loc. 8112 or 8115. Follow-ups may be done after ten (10) working days upon receipt. Per FDA Memorandum Circular 2013-028, follow-ups shall be entertained after the processing time.*

14. Can a product with an expired Certificate of Product Registration but with pending renewal be applied for Sales Promotion?
>>*No. Only products with valid CPR may be applied for sales promotion (per RA 9711 Article V Section 2). The company may apply for promotions once the renewed CPR has been released.*

15. When is a notice or invitation for promo supervision/attestation of an authorized DOH-FDA representative submitted?
>>*Seven (7) working days before the actual activity (per Rules & Regulations Implementing RA 7394).*

FREQUENTLY ASKED QUESTIONS

FOOD SAFETY UNIT

1. What are the issuances that are related to the transfer of regulation of processed meat from National Meat Inspection Service (NMIS) to FDA?

>>*Joint Administrative Circular No. 02 s. 2016 or the "Transfer of Functions in the Regulation of Processed Meat" and FDA Circular No. 2016-013 or the "Guidelines on the Implementation of Joint FDA-NMIS Administrative Circular No. 02 on the Transfer of Functions in the Regulation of Processed Meat".*

2. How should I file my application if my products are processed meat? Is there a difference between application for LTO and CPR of processed meat with other processed food products?

>>*There is no difference in the application of LTO and CPR for processed meat with other processed food products. The company will comply with existing guidelines, requirements, and procedures of FDA on filing and submission of applications such as DOH Administrative Circular 2016-0003, FDA Circular No. 2016-004, FDA Circular 2016-014, DOH Administrative Order No. 2014-0030, etc.*

COMPLAINTS

3. What should I do if I have a complaint on the quality of product I bought, e.g. product has foreign matter, open/broken packaging, deteriorated product, or anything that is related to product quality but without safety issue?

>>*You may directly report your complaint to the manufacturer/ distributor of the product, if there are available consumer hotline services (telephone or mobile numbers) or email of the company. If not, you may download and fill out the FDA Product Complaint Form at http://www.fda.gov.ph/advisories-2/others-advisories-pertaining-to-general-category/227368-fda-citizen-s-charter-handling-of-customer-complaints, attach the product picture in all angles, copy of receipts and all related supporting evidences / documents and send to the Food Safety Unit of CFRR at email address foodsafety@fda.gov.ph*

4. What should I do if I have a complaint on food product which may have caused me and my relatives' hospitalization, sickness or injury?

>>*You may report it by downloading and filling-out the FDA Product Complaint Form at http://www.fda.gov.ph/advisories-2/others-advisories-pertaining-to-general-category/227368-fda-citizen-s-charter-handling-of-customer-complaints, attach the product picture in all angles, copy of receipts, and*

medical abstract from the hospital or clinic, medical certificate/ report from physician, and send to the Food Safety Unit of CFRR at email address foodsafety@fda.gov.ph. If you are residing near FDA Alabang, you may bring and submit the sample to FDA. Otherwise, submit it to the nearest FDA accredited laboratory.

5. Where should I file my complaint if I want compensation from the manufacturer/ distributor/ seller of the product?

>>*You may file your complaint at any nearest Acting Consumer Arbitration Office (ACAO) of the Department of Health (e.g. For Metro Manila residence, the ACAO is at DOH-Mandaluyong City).*

6. Where do I file my report against illegal activity related to processing and/or selling of food products?

>>*You may send all the details of your report to info@fda.gov.ph.*
Note: Your information will be treated with utmost confidentiality.

7. If the product being reported is not under the jurisdiction of FDA (i.e. foods from restaurant, catering services, street foods, fast food chains, canteens) and has no medical incident / food poisoning outbreak, where should I report?

>>*You may visit the nearest Local Government Unit in your area, specifically to the City Health Development Office or Sanitation Office and file your report to them.*

FREQUENTLY ASKED QUESTIONS

GENERAL

1. We would like to invite resource speaker/s from FDA-CFRR, to whom should we address the letter or invitation?

>>*Invitation for resource speakers should be directed towards the Office of the Director General for clearance and directive. Address the invitation to:*

NELA CHARADE G. PUNO, RPh
Director General
Food and Drug Administration

2. We imported food products intended for industrial use (i.e. starch for corrugated board, soya oil for paints) however, the BOC is asking us to present FDA Authorization such as CPR and LTO. How should we go about this?

>>*Submit Letter of Intent stating your concern or issue, Affidavit of Undertaking (Original and Notarized) that the product is not for human consumption and supporting documents (i.e. MSDS, Company Profile, COA that product is not food grade, etc.) After evaluation, FDA-CFRR may issue a letter that we pose no objection on the importation of subject product.*

3. There are errors in our printed labels, what do we do?

>>*Submit letter to FDA-CFRR stating error/s and the quantity of labels produced with errors. If the errors in printed label are those regarding expiration date, lot code, and/or nutrition information, CFRR may require the requesting party to conduct remedial labelling to correct the errors.*

4. We will be conducting a company-initiated recall, how should we go about this?

>>*The Market Authorization Holder (MAH) should notify FDA that they will be conducting a product recall. A meeting between the representative/s of the Product Recall Committee and the representative/s of the MAH should be convened to discuss the next steps and the communication/s expected from each party (i.e. FDA-Public Health Advisory; MAH-Product Recall Strategy, etc.). A more thorough discussion is cited in FDA Circular 2016-012.*

ISSUANCES

Issuances	Links
Administrative Order 2014-0029 Rules and Regulations on the Licensing of Food Establishments and Registration of Processed Food, and Other Food Products, and For Other Purposes	https://ww2.fda.gov.ph/attachments/article/194723/AO2014-0029%20-%20Rules%20and%20Regulation%20on%20the%20Licensing%20of%20Food%20Establishement.pdf
Administrative Order 2014-0030 Revised Rules And Regulations Governing The Labeling of Prepackaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984 or the "Rules and Regulations Governing the Labeling of Prepackaged Food Products Distributed in the Philippines, " and For Other Purposes	https://ww2.fda.gov.ph/attachments/article/194724/AO2014-0030%20-%20Revised%20Rules%20and%20Regulation%20Governing%20of%20Prepackaged%20Food%20Product
Administrative Order 2016-0003 Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration (FDA)	https://ww2.fda.gov.ph/attachments/article/303720/Administrative%20Order%20No.%202016-0003.pdf
FDA Circular 2016-014 Procedure for the Use of Electronic Registration (E-Registration) System for Prepackaged Processed Food Products	https://ww2.fda.gov.ph/attachments/article/355437/FDA%20Circular%20No.%202016-014.pdf
FDA Circular No. 2013-010 Revised Guidelines for the Assessment of Microbiological Quality of Processed Foods	https://ww2.fda.gov.ph/attachments/article/17218/FC2013-010.pdf
CAC/GL 23-1997 Guidelines for Use of Nutrition and Health Claims	http://www.fao.org/ag/humannutrition/32444-09f5545b8abe9a0c3baf01a4502ac36e4.pdf
Office Order 22 s. 1991 Guidelines for the Classification of Vitamins and Minerals	https://ww2.fda.gov.ph/attachments/article/29021/OO%2022%20s%201991.pdf
Administrative Order No. 50 s. 2001 Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs	https://ww2.fda.gov.ph/attachments/article/153569/ao%2050%202001.pdf
CFRR Electronic Registration User Manual	https://drive.google.com/file/d/1E_EGhQlulRW0MbeE5HvXvXwpByElDAQF/view

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

SEP 0 8 2014

ADMINISTRATIVE ORDER
No. 2014- 0029

SUBJECT: Rules and Regulations on the Licensing of Food Establishments and Registration of Processed Food, and Other Food Products, and For Other Purposes

I. Rationale/Background

Effective national food control systems are essential to protect the health and safety of consumers. The global environment for food trade places emphasizes on strengthening food control systems and to implement and enforce risk-based food control strategies.

The Department of Health (DOH) through the Food and Drug Administration (FDA) is mandated by Republic Act (RA) No. 10611, otherwise known as the Food Safety Act of 2013, to bear the specific responsibility of ensuring the safety of all food processing and product packaging activities, among others and to develop and issue appropriate authorizations in the form of a license and certificate or registration that would cover establishments, facilities engaged in production and distribution of products.

The FDA through the Center for Food Regulation and Research (CFRR), per RA 9711, shall adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to protect and promote the right to health of the Filipino people. It shall implement a performance-based food safety control management system which shall include, among others: a) the development of food standards and regulations; b) post-market monitoring; c) enforcement of Hazard Analysis Critical Control Points (HACCP) and other risk-based control measures; d) strong participation in Codex and other international standard setting bodies, e) communication of risks and development of interactive exchange among stakeholders; f) establishment and strengthening of food laboratories; g) development of a database on food-borne illness and epidemiological data; h) strengthening R&D capabilities food safety and quality standards; and i) certification of food safety inspectors. Consistent with international food safety measures, FDA is adopting a risk-based approach on product and establishment risk categorization focusing on preventive, rather than corrective strategies.

Consistent with this mandate, the FDA shall ensure food safety through the imposition of food quality standards in the country. Thus, the issuance of this Administrative Order on the Licensing of Food Establishments, and Registration of Processed Food to issue appropriate authorizations in the form of a permit, license and certificate of registration or compliance that would cover establishments, facilities engaged in packing, holding or producing food for consumption in accordance with the mandated issuances of regulatory agencies issuing such authorizations.

II. Objectives

1. Adoption of risk-based classification of food establishments and food products as published by the Food and Agriculture Organization of the United Nations;

2. The issuance of License to Operate (LTO) to food establishmentsengaged in the manufacture or processing and distribution, i.e. import, export or wholesale, or trade and repacking of processed food and food products, and

3. The issuance of the Certificate of Product Registration (CPR) to FDA-licensed establishments before processed food and other food products are sold, offered for sale or use, distributed or supplied, among other marketing and promotional activities.

III. Scope and Coverage

This Administrative Order covers food establishments engaged in the manufacture and/or distribution, (i.e. import, export and/or wholesale) trade and/or repacking of processed food and food products.

This Administrative Order shall not cover fresh or raw food derived from plant, animal, fisheries and aquaculture products or foods in the primary production and post-harvest stages of the supply chain under the Department of Agriculture. It shall likewise not cover food businesses such as, but not limited to, activities in slaughter-houses, poultry dressing plants, fish ports, wet markets, supermarkets, school canteens, restaurants, catering establishments, water refilling stations, street food sale, including ambulant vending which are under the purview of the Local Government Units (LGUs).

IV. Definition of Terms

For the purpose of this issuance the following terms are defined:

1. Activity refers to either processing, packaging, repackaging, trading, import, wholesale, export, sale, promotion, or offer for sale, of a food product.

2. Advertising refers to the business of conceptualizing, presenting or making available to the public, through any form of mass media, fact, data or information about the attributes, features, quality or availability of food and its related products for the purpose of promoting its sale or distribution and enhancing economic activity.

3. Authorization refers to the permission embodied in a document granted by a regulatory agency to a natural or juridical person who has submitted an application for a food business operation from primary production, post-harvest handling, distribution, processing, manufacture, importation, exportation, sale, and offer for sale, transfer and preparation for human consumption. The authorization can take the form of a permit, license, certificate of registration and certificate of compliance or exemption or any similar document.

4. Bottled Water means water that is placed in a sealed container or package and is offered for sale for human consumption as drinking water.

5. Certificate of Product Registration (CPR) is an authorization issued by the FDA for specific health products after evaluation and approval of submitted registration requirements.

6. Contaminant refers to any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop industry, animal husbandry and veterinary medicine) post-harvest handling, manufacturing, processing, preparation, treatment, packing, packaging, transport or holding of such food as a result of environmental contamination.

7. Control measure refers to any action and activity that can be used to prevent or eliminate food safety hazard or to reduce it to an acceptable level.

8. Distribute means the delivery or sale of any health product for purposes of distribution in commerce, except that such term does not include the manufacture or retail of such product.

9. Distribution means any activity where a food product is stored by an establishment and/or transported to another establishment, with the intention of possible further retail.

10. Distributor/Importer/Exporter refersto any establishment that imports or exports raw materials, ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer.

11. Distributor/ wholesaler refers to any establishment that procures raw materials, and/or finished products from local establishments for local distribution on wholesale basis.

12. Establishment means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of health products, including the facilities and installation needed for its activities.

13. Export refers distribution outside of origin by crossing international borders.

14. Food refers to any substance or product whether processed, partially processed or unprocessed that is intended for human consumption. It includes drinks, chewing gum, water and other substances which are intentionally incorporated into the food during its manufacture, preparation and treatment.

15. Food Additive refers to any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological

(including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.

16. Food-borne illnesses refer to diseases, usually either infectious or toxic in nature, caused by agents that enter the body through the ingestion of food.

17. Food Business refers to any undertaking, whether public or private, which carries out any of the activities related to, or any of the stages of the food supply chain.

18. Food Business Operator refers to a person engaged in the food business including one's agents and is responsible for ensuring that the requirements of the Food Safety Act of 2013 are met by the food business under one's control.

19. Food/ Dietary Supplement refers to a processed food product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamin, mineral, amino acid, herb, or other dietary substance of botanical, animal, artificial or natural origin to increase the total daily intake in amounts conforming to the latest Philippine recommended energy and nutrient intakes or internationally agreed minimum daily requirements. It is usually in the form of capsules, tablets, liquids, gels, powders or pills and is not represented for use as a conventional food or as the sole item of a meal or diet or a replacement for drugs and medicines.

20. Fortification means the addition of nutrients to processed foods or food products at levels above the natural state.

21. Good Manufacturing Practice (GMP) refers to a quality assurance system aimed at ensuring that products are consistently manufactured, packed, repacked or held to quality standards appropriate for the intended use. It is thus concerned with both manufacturing and quality control procedure.

22. Good Distribution Practice (GDP) or Good Storage Practice (GSP) refers to a part of quality assurance system where appropriate procedures for sanitary handling of food on storage and distribution are established. Storage and transportation of finished food should be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container. Warehouses are kept free from rodents, insects, birds and other pests.

23. Hazard Analyses and Critical Control Points (HACCP) refer to a science-based system which identifies, evaluates and controls hazards which are significant for food safety at critical points during a given stage in the food supply chain.

24. Import refers to the distribution into a localdestination by crossing international borders.

25. Ingredient is any substance including food additive, used as a component in the manufacture or preparation of a food and present in the final product in its original or modified form.

26. Inspection refers to the examination of food, food production facilities or establishments, and the management and production systems of food businesses, including the examination of documents, finished product testing and registration, and of the origin and destination of production inputs and outputs to verify compliance with legal requirements by an agency mandated to perform food safety regulatory and/or enforcement functions.

27. Label refers to the display of written, printed or graphic matter upon the immediate container, tag, literature or other suitable material affixed thereto for the purpose of giving information as to identify components, ingredients, attributes, directions for use, specifications and such other information as may be required by law or regulations.

28. Licensing means the process of approval of an application to operate or establish an establishment prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.

29. Local Government Unit (LGU) shall mean the city or municipality, provincial or regional government unit which issues the Sanitary Permit in compliance with the National Sanitation Code of the Philippines and the Mayor's Permit.

30. Manufacturer means an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packaging, repacking, altering, ornamenting, finishing and labelling with the end in view of its storage, sale or distribution. A trader shall be categorized as manufacturer. They may also manufacture products for institutional use. In case of imported food products, the manufacturer's representative or, in his absence, the importer, shall be deemed the manufacturer.

31. Monitoring refers to the systematic gathering of data through the sampling of commodities as well as monitoring of food-borne diseases, collation and interpretation of collected data.

32. Packaging refers to an activity where a product is contained AND SEALED with the intention of storage and/or transport.

33. Packer refers to food manufacturer engaged in packaging food products not previously packaged.

34. Permit refers to a form of authorization that is issued by the FDA to an establishment that has complied with the application requirements.

35. Processing refers to any action that substantially alters the initial raw materials or product or ingredients including, but not limited to, heating, smoking, curing,

maturing, drying, marinating, extraction, extrusion, freezing, fermentationora combination of those processes intended to produce/ manufacturefood.

36. Raw materials are all substances that are employed in the processing of a finished product, packed in bulk containers and not labelled as finished product. Raw Materials or ingredients would have product specifications that comply with the client requirements and not necessarily a single component.

37. Repackaging refers to a manufacturing activity where a food product is taken out of a larger or bulk packaging and again contained with the intention of further storage, transport and distribution.

38. Repacker means any establishment engaged in the process of packaging or changing of container, wrapper (that may include or not a changing of label) from a bulk material to retail packaging sizes in furtherance of distribution of food.

39. Retailer means any establishment which sells or offers to sell any health product directly to the general public.

40. Risk refers to a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

41. Salt Iodization refers tothe addition of iodine to salt intended for human consumption in accordance with specifications as to form, fortificant type, method, manner and composition as may be prescribed by the FDA.

42. Source refers to any establishment able to supply food products to another establishment through further importation, wholesale or export.

43. Trader means any establishment which is a registered owner of food and food products and/or procure the raw materials and packing components, quality control standards and procedures, but subcontracts the manufacture of such product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.

44. Toll Manufacturer refers to the manufacturer that conduct contract manufacturing where conditions of the contract are defined, agreed and controlled; and all aspects of contracted work are specified to obtain quality product/s conforming to the agreed standards.

45. Wholesale refers to local distribution of pre-packaged food productsin commercial quantity.

V. Guidelines for Licensing of Food Establishments

A. General Principles

1. Risk classification of establishments shall be defined by the current issuance from the Food and Drug Administration, and consistent with the current guidelines of the Food and Agriculture Organization of the United

Nations. The FDA shall issue authorization based on risk categorization of food establishments and food products. Food establishments classified as high risk shall be the priority for inspection. (Annex A)

2. All food establishment shall secure a License to Operate (LTO) before engaging in food manufacturing, importation, exportation, sale, offer for sale, distribution, transfer and where applicable the use, testing, promotion, advertisement, and/or sponsorship of food products.

3. The following indicates the activities allowed to under a single license and Table 4 in Annex B summarizes the hierarchies of activities:

   a. A manufacturer may engage in any activity it is able to satisfy the requirements for, including processing;
   b. A packer or repacker may engage in any activity it is able to satisfy the requirements for, except processing;
   c. A trader may engage in any activity it is able to satisfy the requirements for, except processing or packaging;
   d. A distributor is not allowed to engage in processing and/or packaging;
   e. A distributor with a license for a specific activity may engage in other distributor activitiesit is able to satisfy the requirements for;
   f. Distributor activities may be applied for by a manufacturer or distributor,at the same time as the license or later added as an amendment after licensing; and
   g. Multiple facilities within the same address engaged in different activities in the manufacture and distribution of a single product may be associated to a single license.

4. All applications for a License to Operate shall be accepted by the FDA only when all the requirements have been completed.

5. Food establishment shall first apply for LTO initial application. Once the FDA-LTO is secured, CPR initial application should be filed.

6. The LTO shall be a requirement before a food establishment can join food trade and exhibitions, market research or testing of unregistered processed food products.

7. An entity, natural or juridical person, applying for LTO as a food manufacturer, distributor, importer, exporter, wholesaler, trader or repacker shall be issued the LTO only when they have complied with all the necessary requirements.

8. Applicants must prove their capability and capacity to assure food safety and quality through compliance with Good Manufacturing Practice, Good Distribution Practice, Good Storage Practice, Hazard Analysis and Critical Control Points, and/ or other best industry practices recognized by the

Food and Agriculture Organization and the World Health Organization, as appropriate.

9. All FDA-licensed food establishments shall be primarily responsible for determining the regulatory requirements of the importing country before engaging in food export.

10. Licensing of food establishments shall be issued only by the FDA if these are able to demonstrate consistency in manufacture and/or distribution of safe and quality products.

11. Only one licensed establishment should operate at a given address or facility. Establishments engaged in the same activity are not allowed to share the same address or facility, regardless of ownership.

12. Valid LTO shall be displayed in a conspicuous place in the establishment or business office or premises. Failure to display the valid LTO shall be ground for revocation of the LTO.

13. No application for initial or renewal of LTO shall be accepted or approved unless the prescribed fee is paid.

14. For changes of Business Information, no change in the previously approved circumstances of the application of the establishment, such as but not limited to: location, business name and owner, additional or reduction in the product lines, inclusion or deletion of any activities/products, shall be effected unless with prior notification to FDA through amendment.

15. For assignment and Transfer of Pending Applications, Existing Licenses, if there is a change in ownership while application is on process, the application shall be considered terminated and documents shall be returned to the authorized representative of the company. The new owner or the new regulatory officer shall comply with the requirements for initial application including attendance to QPIRA.

16. For licensed establishments with revoked/ cancelled/ suspended LTO resulting from violations as stated in this Order and/or in RA 9711 and/or other relevant food regulations, and after due process, shall not be allowed to re-apply for a new LTO for a period of three (3) years and from using the same of business name.

17. FDA-licensed food establishments or food business operators shall comply with relevant laws that address nutritional quality of food and food products, such as the RA 8172 (ASIN Law) and RA 8976 (Food Fortification Act).

18. Food business operators shall comply with the provisions of RA No. 9711, RA No. 10611, RA No. 3720 as amended by E.O. 175, RA No. 7394, and Presidential Decree No. 856 to ensure food quality and safety.

B. Specific Guidelines for Manufacturers including Traders:

1. Food manufacturing or processing plant shall be covered by a singleLTO notwithstanding their distance or different locations within one locality/municipality/city but with one product, at different stages of operation/ process indicating their address in the license. In this instance, the principal office address shall be reflected at the front page of the LTO while the other address/es at the back page thereof or secondary page appended thereto.

2. When a food manufacturing or processing plant carries an entirely different and complete stage of operation for different products in different locations but within one municipality/city, in which case, each shall be covered by separate licenses. Food manufacturing establishments utilizing or sharing one facility shall not be allowed regardless of ownership.

3. FDA-licensed food manufacturers shall be allowed to import raw materials or finished products as ingredients or additives for their own use to manufacture registered food products. However, for raw materials covered by Republic Act (RA) 8976 (Food Fortification Act) and its IRR and other related issuances including RA 8172 (ASIN Law), these shall comply with the requirements set forth upon importation, such as results of analysis and/or inspection and others as deemed necessary.

4. For Bottled drinking water, the Standards and Good Manufacturing Practice (GMP) requirements as stated in Administrative Order No. 18-A s. 1993 or the Philippine National Standard for Bottled Drinking Water or their amended version shall be followed.

C. Specific Guidelines for Distributor (Importer/ Exporter/ Wholesaler)

1. Any establishment applying for a license to the FDA as food distributor (importer, exporter, wholesaler) utilizing or sharing one office with another establishment shall not be allowed regardless of ownership.

2. For offices of distributors, all warehouses and depots shall be declared. Sharing of offices by different distributors shall not be allowed.

3. Importers shall comply with applicable law, rules and regulations, such as the RA 8172 (ASIN Law) and RA 8976 (Food Fortification Act).

4. An establishment with LTO as food distributors, i.e. as importer, exporter or wholesaler, may engage in manufacturing or repacking provided that a LTO as manufacturer (repacker) shall be secured also from the FDA. Application requirements as listed in succeeding sections relative to this activity shall be submitted to the FDA.

5. Exporters should satisfy the requirements of the importing country prior to export.

D. Requirements

The requirements for issuance of License to Operate and its amendments are specified in Annex C of this Issuance.

E. Validity of the LTO

1. Unless revoked, the LTO shall have the following validity period:
   a. An initial license issued shall be valid for two (2) years
   b. A renewed license shall be valid for five (5) years.

F. Process of Application – The process of application is as prescribed by current FDA regulations and shall be guided by the following:

1. A Certificate of Compliance shall be issued by the FDA inspectorate in the respective regions. Should a site inspection or pre-licensing inspection be required, the inspection shall be scheduled with the applicant, before the Certificate of Compliance is issued.

2. Approval or disapproval of applications with COCs shall be signed by the Director of the Center for Food Regulation and Research under the authority of the FDA Director General.

   However, "Upon finding, in the course of its evaluation, monitoring, inspection and spot checking, of any violation in the compliance and other requirements required by the FDA and its implemented laws, such as the FDA Act of 2009, these Rules and Regulations, and other relevant laws, to submit a report to serve as basis for the *motu proprio* action of the Director of the Regional Field Office;" as per Book I Article VIII of IRR of RA 9711 under Section 7 (g). Hence, the RFO upon verification/inspection that the food establishment has not complied with the requirement have the power to disapprove and sign the proper action by the Director of the RFO.

3. The notice of disapproval of applications for license shall clearly state the reason for disapproval.

VI. Guidelines in the Registration of Processed Food Products

A. General Principles

1. All processed food products including food additives, food supplements and bottled water, shall first be registered with the FDA before these are distributed, supplied, sold or offered for sale or use and advertised, among other marketing or promotional activities.

2. Only one (1)Certificate of Product Registration CPR shall be issued to a product that has multiple packaging sizes provided that it meets all of the following conditions:
   a. The same brand name;
   b. The same product name/ variant;

c. The same product formulation/ ingredients in the same order of proportion; and
d. The same label information, except net weight.

3. Likewise, regardless of the packagingsizes, only one (1) CPR shall be issued to a product that has multiple artwork design and/or multiple suggested recipes on the pack provided that it meets all of the following conditions:
   a. The same brand name;
   b. The same product name/ variant;
   c. The same product formulation/ ingredients in the same order of proportion; and
   d. The same label information except net weight.

4. The company should secure permission from FDA through notification for any additional label design or other label changes prior to use in advertisement, promotion, and commercial distribution.

5. Should a product fail to meet the requirements for product registration, applicable product standards, and labeling regulations, a Letter of Denial shall be issued. The applicant shall be given a maximum of six (6) months to comply and file for re-application.

6. Imported and locally manufactured raw materials, ingredients and food additives which are intended to be sold, offered for sale or use or for distribution to other food establishments and food business operators and consumers shall secure a CPR for each by the importer or distributor.

   a. However, local food manufacturers who directly import and use raw materials, ingredients and food additives for their own use or for further processing to manufacture a processed food product, need not secure a CPR for the raw materials, ingredients and food additives.

7. As stated in Item 6 above, when a CPR is granted to a food manufacturer/importer, all individual ingredients as part of the FDA-registered product formulation, may be imported without a CPR. However, should the FDA-licensed food manufacturer/importer use or source out local ingredients and food additives, it shall only purchase from FDA-licensed establishments.

8. The registration requirements for food establishments intending to export products are the same. However, food establishments with intention to export, shall comply with all the regulatory standards and requirements of the importing country, including the labelling requirements.

9. A previously registered product initially for local distribution shall be allowed to be exported using the same CPR as long as the following conditions are met and labelling and standards of importing country are likewise met:
   a. The same brand name;

b. The same product name/ variant;
c. The same product formulation/ ingredients in the same order of proportion; and
d. The same label information except net weight.

Notification to FDA shall be made and labels in the language of the importing country shall likewise be submitted.

10. Only food additives listed in the latest Codex General Standards for Food Additives (GSFA) and/or the latest FDA Listing of Food Additives and/or approved pharmaceutical excipients list intended for Food Supplement in pharmaceutical dosage form such as tablet, soft gel capsule and capsule shall be issued a CPR.

11. Validity of Certificate of Product Registration (CPR) will be 2 years minimum to 5 years maximum for initial and 5 years for renewal; provided that upon renewal, its holder conforms with the pertinent standards and requirements including labeling regulations.

12. The FDA may require for additional documents on products that are considered high risk food provided that the reason for the additional requirements is to address uncertainties on safety as deemed necessary through a separate issuance.
    a. High risk products include but not limited to the following: infant formula, milk supplements, foods for infants and young children, foods for special medical purposes, and foods for special dietary uses.

13. In case there is a health issue other than the growth of pathogenic microorganisms or other food safety related incidents (e.g. chemical contamination or adulteration), FDA has the option to impose other requirements through regulatory issuances.

14. In addition to the requirements in the proceeding sections, the FDA may conduct inspection of the manufacturing or processing plant or verification of documents submitted or may require additional documents or evidence to ascertain the safety and/or quality of the product.

B. Quality and Safety Standard

1. Food products shall be evaluated based on the technical documents submitted for safety and quality. Only those food establishments with products that have complied with the requirements and meet the standards for food safety, quality, and labeling, including relevant standards set by the FDA/Codex for specific food category, as applicable, will be issued a CPR.

2. All processed Food Products shall comply with the relevant appropriate/ applicable quality and safety standards, if any.

3. Food establishments or food business operators shall be required to conform with the General Principles of Food Hygiene, including general requirements on sanitation, and as appropriate for the food establishment or food business operation, comply with the relevant standards and requirements of the code of Good Manufacturing Practice, HACCP, Good Storage Practice, Good Distribution Practice, or the Sanitary Standard Operating Procedures.

4. Food establishments shall be required to comply, as appropriate, with the requirements of the ASIN Law and Food Fortification Law, and other issuances related to them and to other food quality and safety standards as adopted or determined by the FDA. Products covered by separate laws (e.g. RA 8172 and RA 8976) requiring the submission of Certificate of Analysis (COA) shall be complied with.

C. Product Claims and Labeling

1. No food samples shall be submitted to FDA provided that the labels are clear and bears the complete label information. However, for food supplements, it is necessary to submit product samples in commercial presentation.

2. Food supplements shall not have curative claims or therapeutic claims. Other claims shall be in accordance to existing and relevant labeling guidelines.

3. Advertising and promotional materials of food establishments and food business operators shall not make curative or therapeutic claims without scientific data or clinical trials to substantiate such claims.

D. Requirements

The requirements for issuance of Certificate of Product Registration and its amendments are specified in Annex D of this Issuance.

E. Validity of the Registration

Unless, revoked within the validity period, the CPR shall be valid for 2 years minimum to 5 years maximum for initial and 5 years for renewal.

F. Registration Process

The Director General of the FDA, upon the recommendation of the Center Director for Food, shall further promulgate the rules and regulations on the procedure for registration:

1. Issuance of CPR shall be based on compliance of the product with applicable standards, requirements and regulations.

2. If the product does not conform with applicable standards, requirements or regulations, a Letter of Denial shall be issued. The applicant shall be given 6 months to reapply by submitting the deficiencies and the complete set of documents. Otherwise, the application is considered as initial.

VII. Inspection and Certificate of Compliance

1. The FDA/CHDwill verify documents submitted and conduct inspection prior to licensing dependent on the safety risk of the products being handled by the establishment.

2. The FDA may conduct inspection in collaboration with the LGUs and any agency or office under the DOH, DA and DILG.

3. Pre-licensing inspection and a Certificate of Compliance (COC) shall be issued, following a risk-based approach or HACCP/GMP requirements depending on the level of risks and complexity of production, among others. The conduct of inspection shall be covered by Quality Manual.

4. In lieu of the COC, for the microenterprise food *manufacturer*, Sanitary Permit (establishment) and Health Certificate (food handlers), as appropriate, which are issued after inspection or examination by the LGU sanitary inspectors or health facilities may be accepted by the FDA.

5. The FDA reserve the right to inspect at any time as routine, spot check of food establishment, or post-market surveillance of the product, or to act on any report of food-borne illness or complaints the FDA receives. Upon validation of non-compliance to FDA safety and quality standards, the FDA CFRR Director shall revoke the LTO and CPR immediately, following due process.

VIII. Grounds for Disapproval of Applications

The following shall be grounds for disapproval of an application:

1. Failure to submit complete or correction to documentary requirements.
2. Failure to meet the appropriate standard or requirement evaluation of documents or inspection of the food establishment offices and premises.
3. Failure to respond to notice of deficiency or to submit documents on time.
4. Misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the law, these Rules and Regulations or appropriate standards.
5. Such other analogous grounds or causes as determined by the FDA.

IX. Fees and Other Charges

Initial and renewal application fees and other charges shall be collected as may be allowed by the existing rules on fees and charges or surcharges.

X. Post-Market Surveillance and Product Monitoring

Post-Market Surveillance and product monitoring shall be conducted by the FDA based on the risks presented by the food products. Samples of products shall be collected for testing, and routine and spot checking of food establishments or food business operators shall be conducted. Food-borne illnesses and epidemiological data shall be studied as basis for planning or instituting measures to reduce food-borne outbreaks. Risk communication in collaboration with other stakeholders shall be heightened to reduce the risk of food borne illnesses brought about by food products. Risk management plan or food safety plan as well as attendance to food safety seminars or training shall be required from food borne operators or food establishments to ensure continuous compliance to food safety standards.

XI. Transition Period

Within six (6) months after the signing of this Administrative Order, the FDA shall streamline the national process and system of licensing and registration in the country with other government agencies to ensure increased protection of the health and welfare of consumers, and availability of processed food and food products in the market.

XII. Separability Clause

If any part or term of provision of this order shall be declare invalid or unenforceable the validity or enforceability of the remaining portions or provisions shall not be affected and this order shall be construed as if it did not contain the particular invalid or enforceable part, term or provision.

XIII. Repealing Clause

All other administrative issuances, bureau circulars and memoranda and other regulations inconsistent with this Order are hereby withdrawn, repealed and /or revoked accordingly.

XIV. Effectivity

This Order shall take effect 15 days after its publication in an official gazette or in a newspaper of general circulation.

ENRIQUE T. ONA, MD, FPCS, FACS
Secretary of Health

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

SEP 0 8 2014

ADMINISTRATIVE ORDER
NO. 2014 – 0030

SUBJECT: **Revised Rules And Regulations Governing The Labeling of Prepackaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984 or the "Rules and Regulations Governing the Labeling of Pre-packaged Food Products Distributed in the Philippines," and For Other Purposes**

I. RATIONALE

Administrative Order No. 88-B series of 1984 was promulgated governing the Rules and Regulations for the Labelling of Pre-packaged Food Products Distributed in the Philippines to establish standards and quality measures for food; to implement the policy of the State to ensure safe and good quality supply of food; and to regulate the production, sale and traffic of the same to protect the health of the people.

With the increasing trade of prepackaged food in the country, its safety must at all times be assured. One effective national food safety and control system is consumer information about the food product through its label.

Product label is the most readily available material to inform the consumer about the product contents, shelf life and traceability, among others. It protects against dishonest or misleading advertising or promotion, and facilitates sound choice to acquire the knowledge necessary to be an informed consumer.

Accordingly, with the aim to provide coherence in the Food and Drug Administration's regulatory system for food establishments and prepackaged food products, this Order is hereby issued amending for this purpose certain provisions of Administrative Order No. 88-B s. 1984 or the "Rules and Regulations Governing the Labeling of Prepackaged Food Products Distributed in the Philippines" and for other purposes.

II. OBJECTIVES

A. To promulgate rules and regulations on the revised labeling guidelines of prepackaged food products in order to protect the consumer against hazards to health and safety and provide information and education to facilitate sound choice in the proper exercise of their rights

B. To establish provisions on the exemption to the requirements of labeling of prepackaged food products which are, in accordance with the practice of trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed

III. SCOPE

This Order covers the labeling of all prepackaged food products, including food supplements, whether locally manufactured or imported into the Philippines.

IV. DEFINITION OF TERMS

For the purpose of this labeling regulation, the term:

1. ***Brand Name*** refers to the name appropriated by the manufacturer, repacker, distributors, trader or importer to distinguish its product in the market.

2. ***Bulk Food Materials*** refers to raw materials, ingredients, and food additives that are packed in wholesale containers either for food industry use for further processing or institutional use or food service or catering business or generally not intended for commercial distribution.

3. ***Container*** means any form of packaging material which completely or partially enclosed the food and includes wrappers. A container may enclose the food as a single item or several units or types of prepackaged food when such is presented for sale to the consumer.

4. ***Country of Manufacture/Country of Origin*** means the country in which the processing is performed shall be considered to be the country of origin for the purposes of labeling (CODEX STAN 1-1985, Amended 2010)

5. ***Directions/Instructions for Use*** refers to the relevant information regarding the reconstitution, preparation and consumption of a food product.

6. ***Expiry or Expiration Date/Use-by-date/ Consume Before (Recommended last consumption date)*** means the date which signifies the end of the estimated period under any stated storage condition, after which the product will not have the quality attributes normally expected by the consumers. After this date the food should not be regarded as marketable.

7. ***Food*** means any processed substance, which is intended for human consumption and includes drinks for human beings, beverages, chewing gum and any substance which have been used as an ingredient in the manufacture, preparation or treatment of food.

8. ***Food Additive*** means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or

otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities. (Codex GSFA 2013)

9. ***Food Allergen*** is any food or ingredient known to cause hypersensitivity that contains protein, peptide derived from any of, but not limited to, the following: milk, egg, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

10. ***Food Authorization Number*** means the number assigned to a particular registered food product as proof that it is permitted or authorized by the Food and Drug Administration (FDA) to be manufactured, imported, exported, sold, offered for sale, distributed, transferred, promoted, advertised, and/or used in sponsorship activities. This refers to both the license to operate (LTO) and the food registration (FR) numbers.

11. ***Food Standard*** is a regulatory guideline that defines the identity of a given food product (i.e. its name and the ingredients used for its preparation) and specifies the minimum quality factors and, when necessary, the required fill of container. It may also include specific labeling requirements other than or in addition to the labeling requirements generally applicable to all prepackaged foods.

12. ***Information Panel*** means that part of the label immediately contiguous to the principal display panel and in the case of rectangular, cylindrical or four-sided (tetra-pack) containers, any of the sides adjacent to the principal display panel except the bottom side which serves as the base of package.

13. ***Ingredient*** means any substance, including a food additive, used as a component in the manufacture or preparation of food and present in the final product (in its original or modified form).

14. ***Label*** means a display of written, printed or graphic matter upon the immediate container of any article and a requirement made by or under authority of existing law that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper of the retail package of such article or is easily legible through the outside container or wrapper.

15. ***Labeling*** means any written, printed or graphic matter (1) upon any article or any of its container or wrappers or (2) accompanying the packaged food.

16. ***Lot*** refers to quantity of food produced under essentially the same conditions during a particular production schedule.

17. ***Lot identification code*** refers to a specific code indicating food produced during a period of time and under more or less the same manufacturing condition.

18. ***Medium Chain Triglycerides (MCT)*** are medium chain fatty acid esters of glycerol, containing 6 to 12 carbon atoms and are constituents of coconut and palm kernel oils.

MCTs are more easily digested, absorbed, and metabolized than long-chain triglycerides.

19. ***Nutrition facts/ declarations*** mean a standardized statement or listing of the nutrient content of a food.

20. ***Nutrition Labeling*** is a description intended to inform the consumer of the nutritional properties of a food.

21. ***Prepackaged*** means packaged or made up in advance in a container, ready for sale to the consumer, or for catering purposes.

22. ***Primary Food Commodity*** means food of plant or animal origin that has not undergone any means of processing.

23. ***Principal Display Panel*** means that part of the label which, either through design or general use, is presented or shown to the consumer under customary conditions of display for retail sale.

24. ***Processed Food*** means the product, resulting from the application of physical, chemical or biological processes to a "primary food commodity" intended for direct sale to the consumer, for direct use as an ingredient in the manufacture of food or for further processing.

25. ***Processing Aid*** means a substance or material not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.

26. ***Product Name*** refers to the name of the food that indicates the true nature of the food and shall normally be specific and not generic.

27. ***Spices*** which include dried aromatic plants, refers to natural dried component or mixture used in food for flavoring, seasoning, and imparting aroma. The term applies equally to spices in the whole, broken or ground form.

28. ***Storage Condition*** refers to the prevailing specified temperature range, humidity and other environmental factors within which optimal stability of the food product is ensured based on laboratory data.

GENERAL RULES AND REGULATIONS

A. Prepackaged Food shall not be described or presented in any label or labeling in a manner that is false, misleading or deceptive or is likely to create erroneous impression regarding its character in any respect.
B. Prepackaged Food shall not be described or presented in any label or labeling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such

a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.

C. Food packages shall be labeled with the required information, of which shall be contained in the principal display or information panel.

D. Every word, figure or statement required to be placed on the label or labeling shall be printed legibly with such conspicuousness and in such terms as to render it likely to be understood under customary condition of purchase and use.

E. Where the label of a food package is so small that it prevents the use of letters of the prescribed size or where it concerns secondary or optional information, letters of proportionately reduced size may be used provided the prescribed particulars are visible and legibly shown and the designated label space is proportional to the size of the package. For other small packages that will not be able to accommodate label information, only the brand name and product name may be indicated. However, these shall not be sold separately or not for retail sale.

F. Claims on the label and labeling materials regarding nutrition and health shall follow the Guidelines in the Use of Nutrition and Health Claims in Food (Bureau Circular 2007-002), Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) and Codex General Guidelines on Claims (CAC/GL 1-1979 revised in 1991) and their subsequent amendments in so far as it does not conflict with existing laws.

G. Claims other than health and nutrition not covered under the Guidelines in the Use of Nutrition and Health Claims in Food (Bureau Circular 2007-002), Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) and Codex General Guidelines on Claims (CAC/GL 1-1979 revised in 1991) and their subsequent amendments shall be evaluated based on submitted substantiation.

VI. SPECIFIC RULES AND REGULATIONS

A. Mandatory Label Information

The labels of all prepackaged food shall bear the following minimum mandatory information:

1. Product Name/ Name of the Food

The product name shall be specific and not generic and shall indicate the true nature of the food.

a. Where a product name or names have been established for a particular food in a Food Standard, any one of the names shall be used.

b. In other cases, a common or usual product name, or in the absence thereof, an appropriate descriptive product name which is not misleading, deceptive, or confusing shall be used.

c. A "coined" or "fanciful" name may be used provided it is not misleading, deceptive or confusing and it accompanies one of the names specified in (a) and (b).

d. For the consumer's better understanding of the true nature and condition of the food, there shall appear in the label either in conjunction with, or in close proximity to the product name of the food, such additional words or phrases, as necessary, to state the type of packing medium, form or style,

and the condition or type of treatment it has undergone (e.g. dried, freeze-dried, concentrated, smoke, reconstituted, etc.).

e. The product name/name of the food shall be presented prominently on the principal display panel in bold type letters and shall be in a size reasonably related to the biggest printed matter on such panel, e.g., trade mark or brand name.

2. Use of Brand Name and/or Trademark

a. If an establishment has a registered brand name or trade mark, it shall be mandatory for the holder or owner of the same to indicate such correct brand name or trade mark in the label of its product, but may not be declared if the product will be used for further processing.
b. Any brand name or trade mark used shall be placed in conjunction with the product name referred in item 1 above and must not be misleading, deceptive, confusing, or is likely to create erroneous impression regarding its character or nature in any respect.
c. No brand name shall be allowed that is identical to those already registered with the Food and Drug Administration in the same product classification or those that is offensive, obscene, scandalous or otherwise contrary to public morals based on AO No.2005-0016 entitled "General Policies and Guidelines Governing Brand Names of Products for Registration with the Bureau of Food and Drug" which shall remain as basis unless amended by future issuances.
d. Identical brand name may be allowed provided that it is authorized by the same brand owner.

3. Complete List of Ingredients

a. Except for single ingredient food a complete list of ingredients shall be declared on the label.
b. The list of ingredients shall be headed or preceded by an appropriate title which consists of or includes the term 'ingredient.'
c. The complete list of ingredients shall be declared in descending order of proportion on either the principal display panel or information panel.
d. Added water shall also be declared in the list of ingredients except when the water forms part of an ingredient such as brine, syrup or broth used in a compound food and declared as such in the list of ingredients. Water or other volatile ingredients that evaporate in the course of manufacture need not be declared.
e. Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by the list, in brackets, of its ingredients in descending order of proportion (m/m).
f. Where a compound ingredient constitutes less than 5% of the food, the ingredients, other than food additives which serve a technological function in the finished product, need not be declared.
g. A specific name, not a collective (generic) name shall be used for an ingredient and unless a general class name would be more informative and

not in conflict with other existing regulations or standards the class names in attached **Table 1** ***Annex A*** may be used.

h. Flavors and flavoring substances whether in any of the category below shall also be declared as part of the list of ingredients. Flavor as classified shall be declared as "Natural Flavor(s)", "Nature – identical flavor(s)" or "Artificial Flavor(s)," respectively. In the case of combination of Natural Flavors and Nature – identical flavors it shall be declared as such or simply as "Flavors."
   1) Natural flavors – flavoring substance derived through appropriate physical processes from spices, herbs, fruits or fruit juices, vegetable or vegetable juices, edible yeast, bark, bud, root, leaf of plant materials, meat, fish, poultry, eggs, dairy products or fermentation products thereof.
   2) Nature – identical flavoring substance – substances chemically derived from aromatic materials or obtained synthetically, which are chemically identical to substances present in natural products intended for human consumption.
   3) Artificial flavoring substances – substances that impart flavor but which have not been identified in natural products or natural sources of flavorings.

i. Any pyroligneous acid or other artificial smoke flavors used as an ingredient in a food shall be declared as artificial flavor or artificial smoke flavor. *Provided that, no* representation may be made, either directly or implied, that a food flavored with pyroligneous acid or other artificial smoke flavor has been smoked or has a true smoke flavor, or that a seasoning sauce or similar product containing pyroligneous acid or other artificial smoke flavor and used to season or flavor other food will result in a smoked product or one having a true smoked flavor.

j. Coloring substances shall be declared by their common name or as "Food Color(s)" or "Color(s)" for those that are derived from or identical with substances derived from plant materials, and as "Artificial Color(s)" for coal-tar dyes or other synthetic chemical compounds.

k. Food additives shall be declared by their common name and their functional categories as provided under Bureau Circular No. 2006-016 or in the latest amendment by the FDA.

l. Processing aids and food additives carried over into food (from another food that was used as an ingredient) at levels less than those required to achieve technological function, need not be declared in the list of ingredients.

4. Net Contents and Drained Weight

a. The net content shall be declared using the metric system of measurement or "SI" (International System of Units) on either the principal display panel or the information panel and in parallel to the base of the package. The Declaration shall be made in the following manner:
   1) For liquid foods, by volume;
   2) For solid foods, by weight, except that when such foods are sold by number, a declaration of count shall be made;

3) For semi-solid or viscous foods, either by weight or volume.

b. Foods packed in a liquid medium normally discarded before consumption shall carry a declaration of drained weight. For the purposes of this requirement, liquid medium means water, aqueous solutions of sugar and salt, fruit and vegetable juices, in canned fruits and vegetables only or vinegar, either singly or in combination.

c. For multi-unit retail packages, a statement of the quantity of contents on the outside package shall include the number of individual units, the net content of each individual unit, and in parenthesis the total quantity of contents of the multi-unit package.

A multi-unit retail package may thus be properly labeled:
"20 x 10 g sachets (net wt. 200 g)" or
"6 x 300 ml bottles (1.8 L or 1000 ml)"

5. Name and address of Manufacturer, Repacker, Packer, Importer, Trader and Distributor

a. The name and address of the manufacturer, repacker, packer, importer, trader or distributor of the food shall be declared on the label of locally manufactured products.

If a manufacturer has plant in many cities and/or towns, the corporate head office address would suffice provided every food package has a code/mark to identify the processing plant where it was produced.

b. If the prepackaged food is not manufactured by the person or company whose name appears on the label, the name must be qualified by "Manufactured for" or "Packed for" or similar expression.

c. For imported products, the complete name and address of importer and the country of origin shall be declared.

d. In the case of products carrying foreign brands or manufactured under license by a foreign company, the name and address of the foreign company, shall be in letters of type and size not bigger than those used for the local company.

e. When a food undergoes processing in a second country which changes its nature, the second country in which the processing is performed shall be considered to be the country of origin for the purposes of labeling.

6. Lot Identification

The lot identification code shall be embossed or otherwise permanently marked individually on the immediate packages or containers. For Prepackaged foods in multi-units retail packages such as candies with surface area less than 10 cm^2 the same may be exempted from the requirements of lot identification code only when sold together with the primary packaging.

7. **Storage Condition**

   For products that need special storage condition other than normal room temperature, the storage condition shall be printed clearly, conspicuously and indelibly on all product label or labeling.

8. **Expiry or Expiration Date/ Use-by-date/ Consume Before Date (Recommended last consumption date)**
   Expiration/expiry date shall be printed clearly, conspicuously and legibly on all product labels (except alcoholic beverages) in the following order: Day, Month, Year. The declaration of day and year are numerical while the declaration of month must be in words to avoid confusion (e.g. Expiry date: 01 January 2012 or 01Jan12).
9. **Food Allergen Information**
   Food allergen information on the label of products containing the following ingredients but not limited to those listed below shall be indicated clearly, conspicuously and indelibly, located directly below the List of Ingredients (e.g. Contains food allergen: egg; or "Allergen Information: may contain____" / "Manufactured in equipment that processes _____"; or similar expression)

   The following ingredients known to cause hypersensitivity shall always be declared:
   a. Cereal containing gluten, i.e. wheat, rye, barley, oat, spelt or their hybridized strain and products of these;
   b. Crustaceans and products of these;
   c. Eggs and eggs products;
   d. Fish and fish products;
   e. Peanuts, soybeans and products of these;
   f. Milk and milk products (lactose included);
   g. Tree nut and nut products;
   h. Sulphite in concentrations of 10mg/kg or more
   i. Such other ingredient as may be included by FDA through appropriate issuance

10. **Direction/ Instruction(s) for Use** shall also be printed, where applicable or as necessary to ensure correct utilization of the food.

11. **Nutrition Facts / Nutrition Information/ Nutritive Value**

    a. The nutrition facts shall be presented in tabulated form as shown in Figure 1 through the declaration of protein, carbohydrates (including dietary fiber and sugar), fat (including saturated fat, trans fat and cholesterol), sodium, energy value or calories. Added Vitamin A, iron and iodine for the products covered by the Food Fortification Program or vitamins and minerals and/or other nutrients like fatty acids and linolenic acids for other products claimed to contain such, shall also be included in the tabulation.
    b. All nutrient quantities shall be declared in relation to the average or usual serving in terms of slices, pieces or a specified weight or volume.
    c. The declaration of nutrients can also be expressed either in unit per serving or % RENI or both.

1) Carbohydrates, protein, fats (cholesterol expressed in *mg*), sugar and dietary fiber, shall be expressed in nearest Gram (*g*). Energy values shall be expressed in Calories (*kcal*). Sodium shall be declared in *mg*
2) Vitamins and minerals shall be expressed in Milligram (*mg*) or Microgram (*mcg* or ≤*µg*). International units (I.U.) shall be used for Vitamins A, D & E
3) Locally manufactured food products intended for local consumption shall also indicate the corresponding Recommended Energy and nutrient intake (RENI) values in actual percentage expressed in whole numbers

Nutrition Facts Serving Size:	
No. of Servings per container/pack:	
Amount per Serving:	% RENI*
Calories (kcal)_____ Calories from Fat_____	
Total Fat (g)	
Saturated fat** (g)	
Trans Fat (g)	
Cholesterol (mg)	
Sodium (mg)	
Total Carbohydrates (g)	
Dietary Fiber (g)	
Sugar (g)	
Total Protein (g)	

*Percent RENI values are based on FNRI reference adult requirement of 19- 29 years old. However, if a product is specifically intended for a different age bracket group, percent RENI values are based on the appropriate FNRI reference requirement.
**For coconut products, Medium Chain Triglycerides (MCTs) is predominant.

Figure 1. Sample Format for Nutrition Facts Declaration

d. For purposes of computing the nutrient content expressed in terms of % RENI the computation shall be based on the Philippine Recommended Energy and Nutrient Intake (RENI) for male adults ages nineteen (19) to twenty nine (29). In cases of food products intended for a specific group, RENI values for the said group shall be made as the basis of RENI declaration and such fact shall be indicated on the label.
e. Nutrients present in amounts less than 2 percent of the RENI shall be indicated by the statement "contains less (or symbol "<") 2% RENI" or by an asterisk referring to this statement.
f. The rules on any use of nutrition claims or health claims in food shall be covered by these rules, and/or the CODEX Guidelines for use of Nutrition and Health Claims under CAC/GL 23-1997, including the latest amendment as applicable, except when any portion of the amendments are contrary to existing national laws and their rules and regulations, in consideration of national policies and interest, in which case these rules shall apply as supplementary.

g. Actual nutrient values or content must be consistent with the nutrient label declarations. However, in consideration of the stability of the vitamins and nutrients, the nutrient content of a food shall in no case be lower than 80 percent % of the value for the nutrient declared on the label at any point in time within the expected shelf-life of the product. Further, where a standard has been set by a special law for a particular product, compliance to the standard is mandatory.

The following tolerance limits shall be applied in nutrient label declarations provided that no related nutrition and health claims are made:

Nutrients	Analytical tolerance*
For energy, fat and carbohydrates	Min. 80% of the declared nutrient value on label and max. 120% of the declared nutrient value on label.
For other nutrients: protein, fiber, vitamins and minerals	Min. 80% of the declared nutrient value on the label

*% refers to the ratio between the nutrient level from actual analytical result and the declared level multiplied by 100

The values used in nutrient declaration should be weighted average values derived from data specifically obtained from analyses of products which are representative of the product being labelled.

h. Nutrition Labeling Exemptions:

1) Foods for Special Dietary Uses and Foods for Special Medical Purposes covered by a separate guideline or Codex Standard;
2) Bottled drinking water which has its own prescribed labeling guidelines;
3) Prepackaged foods in multi-units retail packages such as candies with surface area less than 10 cm^2 may be exempted from the requirements of nutrition labeling when sold together with the primary packaging;
4) Foods served or sold in restaurants which are not labeled or prepackaged available to the consumer (e.g. schools, cafeterias, trains, airplanes and retail stores) for immediate consumption;
5) Foods that contain insignificant amounts of all nutrients to be listed in nutrition labeling (e.g. coffee and most spices, flavor extract, food color, as determined by FDA);
6) Bulk materials for further manufacturing or repacking;
7) Foods in packages with available label space of less than 10 cm^2 (e.g. pack of gum) provided that no health and nutrition claim is made;
8) Food sold from bulk containers except products covered by R.A. 8976, provided that nutrition information is provided at point of sale;
9) Foods for infants and young children such as infant formula, follow-up formula which should follow their own labeling standard;
10) Alcoholic beverages;
11) Other products that may be identified by the FDA through appropriate issuance;

B. Other Requirements

1. **Alcoholic Beverages**
   In addition to the applicable labeling requirements above, the Alcohol content in terms of percentage (%) volume or proof units shall be indicated on the label of alcoholic beverages.

2. **Language**

   The language used for all information on the label shall be either in English or Filipino or a combination thereof. For food products intended for export the language acceptable to the importing country shall be used.

   In the case of imported food products, labels where in the information are declared in a foreign language shall always carry the corresponding English translation.

   In cases of exhaustion of existing labels permitted by the FDA, the use of provisionary sticker label for the English or Filipino translation shall only be allowed for a maximum period of 6 months. All information should be accurate, legible and must be contained in a single sticker. The sticker must be durable, i.e. cannot be easily removed from the label or packaging.

3. **Irradiated Foods**

   The labeling of all food irradiation and all irradiated foods shall follow the guidelines below, as stated in Section 4-E numbers 2 – 4 of Policies and Guidelines as contained in Administrative Order No. 152 s. 2004 entitled Prescribing Regulations for Irradiated Food:

   "4-E. Labeling of Irradiated Food

   2. *The labeling of pre-packaged irradiated food at the retail outlets shall contain the international logo for irradiated food with the statement "treated by irradiation" or its equivalent, in addition to the mandatory labeling information required by BFAD for pre-packaged food.*
   3. *The information required for pre-packaged irradiated food shall be posted and/or conspicuously displayed in the shelves where irradiated food which are not pre-packaged are being displayed for sale to consumers at the retail outlets.*
   4. *Irradiated food for wholesale or distribution to retailers shall be labeled with sufficient information to identify the product and shall be accompanied by documents that will contain the following:*
      a. *Irradiation facility where the products were treated and its address*
      b. *License number of the facility and its validity period*
      c. *Date of irradiation*
      d. *Purpose of irradiation"*

4. Additional Information

Additional information when mandated in a Food Standard or any other FDA regulation or as deemed necessary to assure safety of use shall be indicated on the label. Other declarations on the label shall be substantiated such as Halal, Kosher, organic, etc.

The assigned food authorization number to the food product to be manufactured, imported, exported, and/or distributed may be printed clearly and indelibly, on the principal display panel or information display panel. A sticker may be allowed to reflect the FAN which consists of LTO number and FR number.

C. Labeling of Food Additives

The provisions of the Guidelines of Codex Standard for Food Additives Labeling (General Standard for the Labeling of Food Additives when Sold as such – CODEX STAN 107-1981) are hereby adopted. See attached ***Annex B*** for reference.

VII. MISLEADING DECLARATION/ REPRESENTATION/ PROHIBITED CLAIMS

In addition to the provisions stipulated in Codex Guidelines on the Use of Nutrition and Health Claims and Codex General Guidelines on Claims, any of the following representations or suggestions whether directly or indirectly stated shall constitute misleading, deceptive, and untruthful declaration:

A. That the food because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation or treatment of any disease or symptom of an illness.
B. That a balanced diet of ordinary foods cannot supply adequate amount of nutrients.
C. That the food has dietary properties when such properties are of no significant value or need in human nutrition.
D. That a synthetic vitamin in a food is superior to natural vitamin.
E. Claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.
F. Claims which highlight the absence or addition of any food additive or nutrient supplement, if the addition of such food additive or nutrient supplement is not permitted or prohibited.
G. Claims on the absence of beef or pork or its derivatives or lard or added alcohol are prohibited if the food does not contain such ingredient.
H. Claims on the absence of any substance when the food does not contain such ingredient.
I. Claims that a product is superior to any other existing product of the same kind that cannot be substantiated.
J. Claims stating that any given food will provide an adequate source of all essential nutrients, except in the case of well-defined products for which a Codex standard regulates such claims as admissible claims or where FDA have accepted, through an issuance, that the product to be an adequate source of all essential nutrients. (Codex General Guidelines on Claims CAC/GL 1-1979, Amended 2009, Section 3.1 on Prohibited Claims)
K. Claims as to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition unless they are:

1. In accordance with the provisions of Codex standards or guidelines for foods as developed by the Committee on Nutrition and Foods for Special Dietary Uses and follow the principles set forth in these guidelines; or
2. In the absence of an applicable Codex standard or guideline, permitted by FDA.

L. Meaningless claims including incomplete comparatives and superlatives.
M. Claims as to good hygienic practice, such as "wholesome," "healthful," or "sound"
N. Use of Photographs and Graphic Representations
   1. Photographs of fruits, vegetables, poultry, fish, meat or eggs whether fresh or cooked, whole or sliced shall not appear on the label unless the product contains such materials or substances naturally derived from them. If flavoring substances have been added to boost or reinforce the natural flavor of a given material, the words "Flavor Added" or any statement to that effect shall appear conspicuously and in close proximity to the photograph
   2. Graphic representations used to depict the above mentioned materials (fruits, vegetables, etc.) are acceptable provided these do not vividly illustrate the actual appearance of such materials.
   3. Pictures of food preparations or dishes may appear on the labels of products like sauce mixes or other similar food products that are used as ingredient(s) for the preparation of such food/dishes provided the statement "Serving Suggestion" or any other statement of similar importance appear with the picture.
O. Use of Names of Places
   1. Names of places may be used as part of the name of the product (a) if the product is produced in the place cited or (b) if the product contains the characterizing ingredient(s) and/or prepared in exactly the same manner as the product identified with the said place. However, in the case of (b), if the place cited is in another country, it shall be qualified by the word "style" except when reference to the place is accepted ad a generic term for that product.
   2. Use of names of places as Brand Name is acceptable provided the presentation is not misleading, i.e., it does not appear as part of the name of the product.
P. Such other analogous cases as determined by the FDA.

VIII. EXEMPTIONS FROM THE LABELING REQUIREMENTS

Exemptions from the labeling requirements shall be allowed in the following situations:

A. Food materials to be served in restaurants or to be served in airline catering, which are not labeled and prepackaged available to the consumer (e.g. schools, cafeterias, trains, airplanes and retail stores) and for immediate consumption.
B. Bulk food materials (including raw materials, ingredients and processed food products) for further processing or repacking or for catering or food service use and not intended for retail sale, on condition that these are properly identified as may be appropriate and product specifications are provided in supporting documents.
C. Foods in primary packages with available label space of less than 10 cm^2 (e.g. pack of gum, individually wrapped candies), provided that the secondary packaging contains all the required labeling information.

Exemptions from any specific provision/s of this labeling regulation may be granted under justifiable circumstances as may be determined by the FDA Director General. Petitions for such exemptions should be submitted to the FDA for appropriate action.

Exemptions from any specific provision/s of this labeling regulation may be granted under justifiable circumstances as may be determined by the FDA Director General. Petitions for such exemptions should be submitted to the FDA for appropriate action.

IX. VIOLATIONS AND SANCTIONS

Any violation of the provisions of this Administrative Order shall render the food product misbranded under RA 9711, and such misbranded food products and the responsible person shall be subject to actions and penalties available to the FDA as provided under Republic Act No. 3720 as amended by Executive Order No. 175 and further amended by Republic Act No. 9711 and its implementing rules and regulations.

X. TRANSITORY PROVISIONS

A. For products with existing valid CPR, a non-extendible period of twelve (12) months for exhaustion of old labels will be allowed.
B. For products with pending renewal application, a non-extendible period of twelve (12) months for exhaustion of old labels will be allowed; compliant labels must however be submitted.
C. For new products and products with pending initial application, compliance to these guidelines is mandatory.

After 12 months from the effectivity of this Order, non-compliant products shall thereafter be deemed misbranded and appropriate sanctions against the violating establishment shall be imposed.

XI. REPEALING CLAUSE

Provisions of AO No. 88-B s. 1984 and issuances which are inconsistent to those reflected hereon are modified, and/or repealed accordingly.

XII. SEPARABILITY CLAUSE

If any part or provision of this Revised AO be declared invalid or unconstitutional, such invalidity or unconstitutionality shall not affect the other provisions which shall remain in full force and effect.

XIII. EFFECTIVITY

This regulation shall take effect immediately upon approval and publication in two (2) Newspapers of general circulation.

ENRIQUE T. ONA, MD, FPCS, FACS
Secretary of Health

Table 1. Class Names for Use in Ingredients Listing

NAME OF CLASSES	*CLASS NAMES for Use in Ingredients Listing*
Refined oils other than olive*	'Oil' together with either the term 'vegetable' or 'animal', qualified by the term 'hydrogenated' or 'partially-hydrogenated', as appropriate
Refined fats*	'Fat' together with either, the term 'vegetable' or 'animal', as appropriate provided that for animal fat the specific animal source must be declared (i.e. pork, beef)
Starches, other than chemically modified starches	Starch
All species of fish where the fish constitutes an ingredient of another food and provided that the labeling and presentation of such food does not refer to a specific species of fish	Fish
All types of poultry meat where such meat constitutes an ingredient of another food and provided that the labeling and presentation of such a food does not refer to a specific type of poultry meat	Poultry meat

NAME OF CLASSES	*CLASS NAMES for Use in Ingredients Listing*
All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another food and provided that the labeling and presentation of such food does not refer to a specific type of cheese	Cheese
All spices and spice extracts not exceeding 2% by weight either singly or in combination in the food	'Spice', 'spices', or 'mixed spices', as appropriate
All herbs or parts of herbs not exceeding 2% by weight either singly or in combination in the food	'Herbs' or 'mixed herbs', as appropriate
All types of gum preparations used in the manufacture of gum base for chewing gum	Gum base
All types of sucrose	Sugar
Anhydrous dextrose and dextrose monohydrate	'Dextrose' or 'glucose'
All types of caseinates	Caseinates
Milk products containing a minimum of 50% of milk protein (m/m) in dry matter**	Milk Protein
Press, expeller or refined cocoa butter	Cocoa Butter
All crystallized fruit not exceeding 10% of the weight of the food	Crystallized Fruit

*Not applicable to list of ingredients declaration of fats and oils products

**Calculation of milk protein content: Kjeldahl nitrogen × 6.38

Labeling of Food Additives

The following provisions of the Guidelines of Codex Standard for Food Additives Labeling (General Standard for the Labeling of Food Additives when Sold as such – CODEX STAN 107-1981) are hereby adopted:

1. **Mandatory Labeling of Prepackaged Food Additives Sold by Retail**

The labels of all food additives sold by retail shall bear the information required by sub-sections a.1 to a.6 of this section, as applicable to the food additive being labelled.

Details of the food additive:

A. The name of each food additive present shall be printed. The name shall be specific and not generic and shall indicate the true nature of the food additive. Where a name has been established for a food additive in a Codex list of additives, that name shall be used. In other cases the common or usual name shall be listed or, where none exists, an appropriate descriptive name shall be used.
   1) If two or more food additives are present, their names shall be given in the form of a list. The list shall be in the order of the proportion by weight which each food additive bears to the total contents of the container, the food additive present in the greatest proportion by weight being listed first. Where one or more of the food additives is subject to a quantitative limitation in a food covered by a Codex standard, the quantity or proportion of that additive may be stated. If food ingredients are part of the preparation, they shall be declared in the list of ingredients in descending order of proportion.
   2) In the case of mixtures of flavourings, the name of each flavouring present in the mixture need not be printed. The generic expression "flavour**"** or "flavouring" may be used, together with a true indication of the nature of the flavour. The expression "flavour" or "flavouring" may be qualified by the words "natural", "nature-identical", "artificial", or a combination of these words, as appropriate. This provision does not apply to flavour modifiers, but does apply to "herbs**"** and "spices", wherein generic expressions may be used where appropriate.

3) All food additives shall carry an expiration date which shall signify that beyond this date the effectivity of the additive for its intended use is diminished.
4) The words “For Food Use” or a statement substantially similar thereto shall appear in a prominent position on the label.
5) The words “For Food Use” or a statement substantially similar thereto shall appear in a prominent position on the label.

B. Instructions on storage and use

Adequate information shall be given about the manner in which the food additive is to be kept and is to be used in food.

C. Net contents

The net contents shall be declared in either the metric (Système International Units) or avoirdupois or both systems of measurement as required by the country in which the food additive is sold. This declaration shall be made in the following manner:
1) for liquid food additives, by volume or weight;
2) for solid food additives, other than those sold in tablet form, by weight;
3) for semi-solid or viscous food additives, either by weight or volume;
4) for food additives sold in tablet form, by weight together with the number of tablets in the package.

D. Name and Address

The name and address of the manufacturer, packer, distributor, importer, exporter of the food additive shall be declared.

E. Country of Origin

The country of origin of a food additive shall be declared if its omission is likely to mislead or deceive the consumer.

When a food additive undergoes processing in a second country which changes its chemical or physical nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labelling.

F. Lot Identification

Each container shall be marked in code or in clear to identify the producing

factory and the lot.

2. Mandatory Labelling of Prepackaged Food Additives Sold Other than by Retail

The labels of all food additives sold other than by retail shall bear the information required by Sub-sections C.1.a to C.1.f, as applicable to the food additive being labeled; except that, where the food additives in non-retail containers are solely destined for further industrial processing, the required information, other than that described in Sub-sections C.1.a to C.1.f, may be given on the documents relating to the sale.

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

FEB 15 2016

ADMINISTRATIVE ORDER
No. 2016-0003

SUBJECT: Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration (FDA)

I. RATIONALE

The 1987 Philippine Constitution mandates the establishment of an effective food and drug regulatory system that is responsive to the country's health needs and problems.

Consistent with said constitutional provision, Congress passed landmark legislations, namely Republic Act (RA) No. 3720 (Food, Drugs and Devices and Cosmetics Act), as amended by RA No. 9711 (Food and Drug Administration Act of 2009), RA No. 10611 (Food Safety Act of 2013), and RA No. 9502 (Universally Accessible Cheaper and Quality Medicine Act of 2008) mandating FDA to regulate establishments engaged in health products to ensure consumer safety, welfare protection, and fair trade practice.

In order to improve FDA's effectiveness and efficiency in carrying out its mandate, there is a need to harmonize, unify and streamline its processes and licensing requirements. This will help ensure the availability and accessibility of quality and safe health products in the market.

II. OBJECTIVES

This Order sets the guidelines on a unified, harmonized and streamlined licensing requirements of the Food and Drug Administration to hasten its approval process and strengthen its post-marketing surveillance activities.

III. SCOPE

This Order shall apply to the four (4) FDA Centers – namely, Center for Cosmetics Regulation and Research (CCRR), Center for Drug Regulation and Research (CDRR), Center for Food Regulation and Research (CFRR), Center for Device Regulation, Radiation Health and Research (CDRRHR) – and the Field Regulation Operations Office (FROO).

These guidelines shall cover, the following establishments, whether public or private:

1. Manufacturers, traders and distributors (importers, exporters, and wholesalers) of processed foods, drugs (including vaccine, biologics, veterinary drugs and products), cosmetics, medical devices, in-vitro diagnostic device and reagents, household/urban pesticides, toys, and child care articles; and
2. Drugstores/pharmacies/boticas (including hospital pharmacies and institutional pharmacies), and retail outlets for non-prescription drugs (RONPD).

However, it shall not apply to or cover the following establishments or persons as these are not currently required to secure LTO prior to commencement of their business activity:

1. Retailers or retail outlets of food, cosmetics, medical devices, in-vitro diagnostic devices and reagents and household/urban hazardous substances, toys and child care articles;
2. Operators or applicators of household or urban pesticides;
3. Organizers of national and international trade fairs and exhibits;
4. Organizations or persons engaged in donations, medical missions and other humanitarian activities; and
5. Importers/ Distributors of collector's items

Finally, the application for LTO of the following establishments or persons shall be governed by separate rules and regulations:

1. Sponsors and contract research organizations (CROs) shall comply with Administrative Order No. 2014-0034 and FDA Circular No. 2015-003;
2. Facilities using medical and non-medical radiation devices;
3. Salt manufacturers and distributors governed by RA 8172 (ASIN Law); and
4. Bottled water manufacturer and distributor shall comply with Administrative Order No. 18-A s 1993.

IV. GENERAL GUIDELINES

A. The terms used in this AO shall have the meaning as defined in RA 9711 and its IRR, and related laws and regulation.

B. All establishments covered in this AO shall first secure the appropriate LTO or authorization from FDA prior to engaging in the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertisement and/or sponsorship of any activity that involves health product.

C. All licensed manufacturers are granted an Initial LTO based on the minimum requirements set by FDA in order to operate a manufacturing plant. A Certificate of GMP Compliance shall only be issued upon demonstration of satisfactory compliance to GMP and effective up to the validity of the current LTO. Thereafter, the Certificate of GMP Compliance shall be issued each time the LTO is renewed.

D. All covered establishments must continuously comply with the existing requirements, regulations and standards, otherwise they may be ordered closed or their licenses be suspended or revoked *motu proprio*, or upon petition by any affected person. A violation with any of the terms and

conditions of the LTO may result in the suspension, revocation or cancellation of the LTO, or disapproval of its application for renewal.

E. All covered establishments shall be under the supervision of a qualified person(s) as required by pertinent rules and regulations (refer to Annex A).

F. The FDA shall have the authority to enter any covered establishment for (1) inspection and/or (2) verification of documents submitted to FDA in support of its application for license.

G. The responsibility of ensuring the safety, quality, and when applicable, the efficacy and/or purity of health products, shall rest upon all the establishments or persons involved in the production, sale, handling, packing, transport, distribution, trading and storage thereof.

V. SPECIFIC GUIDELINES

A. In case the health product has been banned or withdrawn for health and safety reasons in the country of origin, the importer shall immediately undertake the necessary measures in banning from the public its sale, distribution or donation, or its immediate recall, withdrawal or seizure from the market.

B. Establishments engaged in health product that is declared by FDA to be injurious, unsafe or dangerous are required to immediately recall, withdraw, or seize the product, or ban its sale, distribution or donation to the public.

C. For drug establishments:

1. All drug establishments engaged with vaccines, biologics and other temperature-sensitive drug products shall comply with the cold chain management requirements.

2. All drugstores, whether privately owned or government-owned, shall be under the supervision of a registered pharmacist when operating or open for business, unless otherwise allowed by other pertinent laws or regulations.

3. All FDA-required information, education and communication campaign material shall be displayed in the establishment's conspicuous area.

D. All approved LTO applications shall be sent through courier directly to the establishment's owner, president, CEO, general manager or equivalent responsible officer as indicated in the application form.

VI. PROCEDURE

A. Application Requirements

The following are the requirements for application of a License to Operate (LTO).

1. Initial Application

(a) Accomplished Application Form and Declaration and Undertaking
(b) Proof of Business Name Registration
(c) Site Master File (for manufacturers of drugs, devices and cosmetics)
(d) Risk Management Plan
(e) Payment

2. Renewal Application

(a) Accomplished Application Form with Declaration and Undertaking
(b) Payment

Guidance for the above requirements is attached as Annex "A".

B. Application Process

1. Filing

An application for LTO, whether initial, renewal, or variation, and other authorizations are deemed filed upon submission of complete requirements including payment of required fees and charges.

2. Evaluation

The evaluation of all applications for LTO shall be based on the veracity of the submitted documents and compliance with appropriate standards.

In case the applicant falsified, misrepresented material facts or documents, or withheld any material data or information, the application shall be disapproved. In such cases, the applicant may be investigated, appropriate charges may be filed, and penalties may be imposed.

Should there be a need for clarification on the application, a notification, either written or through e-mail, shall be sent to the applicant.

3. Inspection

Pre-opening inspection shall be mandatory for manufacturers. All covered establishments may be inspected at any time by FDA as part of its post-marketing surveillance activities.

C. Variations

Variations shall require prior FDA approval. Variations may either be major or minor.

1. Major variation covers changes in the operations of the establishment that may affect significantly and/or directly the aspects of safety and quality and when applicable, efficacy of products.

   Major variation shall only be approved upon proper notification, compliance to requirements and inspection.

2. Minor variation covers changes in administrative matters and/or changes in the operations of the establishment but with minimal impact on the safety, quality and, when applicable, the efficacy of products.

The list of variations, the conditions, and the documentary requirements is attached as Annex "B".

The FDA Director-General may issue orders to categorize certain variations which are not included in the enumeration as either major or minor variation.

D. Validity and Fees

The validity of LTOs and the applicable fees and other charges shall be covered by separate issuances.

E. Cancellation of License to Operate

1. Automatic. Existing establishments that fail to file an application for renewal after one-hundred twenty (120) days from the date of expiration shall be automatically cancelled and deleted from the list of licensed establishments without prejudice to their re-application.

2. Voluntary. The owner or authorized person of a licensed establishment may apply for voluntary cancellation of its existing license by filing a formal notification with the FDA.

3. Cancellation as a Penalty. The FDA may also impose the penalty of cancellation of license.

4. When the license is cancelled either automatically or voluntarily, the FDA shall retain jurisdiction over violations committed by the establishments while it was in operation.

5. All establishments shall settle all their monetary obligations to FDA.

F. Accessibility

The relevant forms, requirements for application, and the submission process shall be made accessible at the FDA Website.

VII. PENALTY CLAUSE

Sanctions over violations of any of the provisions of this Administrative Order shall follow the Rules of Administrative Procedure provided in the implementing rules and regulations of Republic Act No. 9711.

VIII. REPEALING CLAUSE

All issuances, or parts thereof, pertaining to LTO applications covered by this Administrative Order are hereby repealed.

IX. SEPARABILITY CLAUSE

If any portion or provision of this Order is declared invalid or unenforceable or unconstitutional, the validity or enforceability of the remaining portions or provisions shall not be affected, and this Order shall be construed as if it did not contain the particular invalid or unenforceable or unconstitutional portion or provision.

X. MANDATORY REVIEW

This Administrative Order shall be reviewed by FDA after two (2) years of its implementation.

XI. EFFECTIVITY

This Administrative Order shall take effect on 01 March 2016 following its publication in 2 newspapers of national circulation and submission to the University of the Philippines Law Center.

For drugstores and RONPDs, mandatory submission of RMP will be effective on January 1, 2017.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health

ANNEX A
Guidance LTO Application

A. The establishment's owner, president, chief executive officer (CEO) or authorized officer and its qualified person shall sign the application form. The authority of the signatories shall be evidenced by any of the following:

1. Single Proprietorship – Power of Attorney when the authorized representative is not the owner of the establishment;
2. Corporation and Cooperative – Secretary Certificate or Board Resolution;
3. Partnership – Partnership Resolution; or
4. Government Agency – Authority from the Head of Agency.

B. The documentary requirements for submission:

1. Accomplished Application Form
   Among other information, the application form shall contain the following:

   (a) Declaration and undertaking of the responsibilities of the applicant as a condition for the processing and approval of the LTO;
   (b) The location plan and global position system (GPS) coordinates of the establishment;
   (c) The name of the qualified person per type of establishment, and the relevant credentials (e.g. PRC ID):

Type of Establishment	Qualified Person	Credential/s
Drug Establishment:	Pharmacist	☐ PRC ID ☐ Attendance to FDA appropriate Licensing Seminar
	Responsible pharmacy assistant (for drugstore and RONPDs)	☐ Certificate of Training
Food Establishment	Food Safety Compliance Officer or Regulatory Officer	☐ Certificate of Attendance to appropriate FDA Licensing Seminar ☐ Certificate of Attendance to GMP, HACCP, or Food Safety Seminar
Medical Device Establishment	Pharmacist or Any Other Qualified Professional	☐ PRC ID or any Proof of Qualification ☐ Attendance to medical device QPIRA
Cosmetic Establishment	Pharmacist or Any Other Qualified Professional	☐ PRC ID or any Proof of Qualification ☐ Attendance to QPIRA

(d) The names of the following personnel shall also be listed:

Type of Establishment	Other Qualified Person
Drug Manufacturer:	(a) Production Manager/Head (b) Quality Assurance Manager/Head (c) Quality Control Manager/Head (d) Authorized person for batch release (e) Pharmacovigilance Officer
Other Drug Establishments	(a) Pharmacovigilance Officer
Food Manufacturer	(a) Production Manager/Head (b) Quality Assurance Manager/Head (c) Quality Control Manager/Head (d) Food Safety Officer (e) Any designated senior technical personnel
Medical Device Establishment	(a) Production Manager/Head (b) Quality Assurance Manager/Head (c) Quality Control Manager/Head
Cosmetic Establishment	(a) Production Manager/Head (b) Quality Control and/or Assurance Manager/Head

2. Proof of Business Name Registration

The business name/registration must be evidenced by copies of the following:

(a) For single proprietorship – Certificate of Business Registration issued by the Department of Trade and Industry (DTI);
(b) For corporation, partnership and other juridical person – Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation;
(c) For cooperative – Certificate of Registration issued by the Cooperative Development Authority and Articles of Cooperation; or
(d) For government-owned or controlled corporation – the law creating the establishment, if with original charter, or its Certificate of Registration issued by the Securities and Exchange Commission (SEC) and Articles of Incorporation, if without original charter.

The document must indicate the exact and complete address, e.g., unit number, floor, building, lot, block, phase, street, barangay, city/ municipality, province, where applicable.

In case the business address of the applicant is different from the one indicated in its business name registration, the applicant must submit a copy of its valid Business Permit.

3. Site Master File[1] (for manufacturers of drugs, devices and cosmetics except traders)

As required by the applicable good manufacturing practice (GMP) for the type of establishment.

4. Risk Management Plan (for manufacturers and distributors of drugs and medical devices establishments, and drugstores and RONPDs)

A general Risk Management Plan (RMP) for the establishment must be submitted. The RMP shall contain details on how to identify, characterize, prevent or minimize risk relating to the products that the establishment is engage with. These shall include post-marketing surveillance activities and interventions to manage the risks.

5. Payment

Proof of payments (e.g., official receipt or authorized bank payment slip) must be attached to the application.

[1] Site Master File refers to a document prepared by the manufacturer and contains specific information about the quality management policies and activities of the site, the production and/or quality control of manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby buildings. It provides clear information on the manufacturer's GMP related activities that are useful in general supervision and in the efficient planning and undertaking of GMP inspections.

ANNEX B
LIST OF REQUIREMENTS FOR VARIATION APPLICATIONS FOR ESTABLISHMENTS

A. Major Variation[2]

Transfer of Location of Manufacturing Plant and Drug Retailers	
C	1. Physical transfer of the establishment (and may entail changes in the previously approved address). 2. Other variations (e.g. change of pharmacist or qualified personnel, and/or business name) may also be included in the application for variation provided that that same are indicated therein and the corresponding requirements for such changes are included.
D	1. Application Form 2. Business permit reflecting the new address 3. Updated Site Master File 4. Payment

Expansion of Manufacturer	
C	1. Shall refer only to the expansion made which is adjacent to the existing location of the establishment and no additional product line is involved. 2. Expansion shall also include additional floors for production.
D	1. Application Form 2. Updated Site Master File 3. Payment

Additional Production Line	
C	An additional production line is an added type or class of products produced within the same manufacturing site (e.g., sterile line, beverage line, etc.)
D	1. Application Form 2. Updated Site Master File 3. Payment

Change of Manufacturing Activity	
C	1. Shall refer to an additional activity that the manufacturer engages in (e.g. LTO as Manufacturer with additional activity as Repacker) 2. Shall also refer to a change of previously licensed activity (e.g. LTO as Manufacturer-Repacker to Manufacturer-Packer).

[2] Major variation refers to post-FDA approval changes in the status, condition or activity of a licensed establishment where inspection is required prior to approval of variation.

D	1. Application Form 2. Updated Site Master File 3. Payment

Transfer/Addition of Warehouse	
C	1. Shall refer to the physical transfer of warehouse. 2. Shall also refer to an addition of warehouse aside from the existing and previously inspected warehouse by FDA.
D	1. Application Form 2. Business permit reflecting new warehouse 3. Payment

B. Minor Variation [3]

Transfer of Location of Offices	
C	1. Physical transfer of the office of the establishment (which may also entail changes in the previously approved address). 2. Other variations (e.g. change of pharmacist or key personnel, and/or business name) may also be included in the application for variation provided that that same are indicated therein and the corresponding requirements for such changes are included.
D	1. Application Form 2. Business permit reflecting the new address 3. Payment

Change of Distributor Activity	
C	1. Shall refer to an additional activity that the distributor engages in (e.g. LTO as Distributor-Importer with additional activity as Exporter) 2. Shall also refer to a change from the initially licensed activity (e.g. LTO as Distributor-Importer to Distributor-Exporter).
D	1. Application Form 2. Contract Agreements to prove activity 3. Payment

Expansion of Office Establishments and Drug Retailers	
C	1. Shall refer to the expansion made which is adjacent to the existing location of the establishment. 2. Expansion shall also include additional floors where the building is occupied.

[3] Minor variation refers to changes in the status, condition or activity of a licensed establishment which are not critical to the safety or qualify, or in the purity or efficacy, when applicable, of the health product.

D	1. Application Form 2. Payment

Additional Drugstore Activity	
C	1. Additional activity shall include online ordering and delivery, sterile compounding and non-sterile complex compounding, mobile pharmacy, carrying of medical devices, and other additional activities that may require appropriate regulation or may be handled on a case to case basis. 2. These additional activities may already be included in the initial application.
D	1. Application Form 2. Additional Credentials of Pharmacist (e.g. Certificate of Training, where applicable) 3. Documents related to activity with proof of validation (e.g. SOP, Masterlist of compounding recipes) 4. Payment

Change of Ownership	
C	There is a change of ownership of the licensed establishment.
D	1. Application Form 2. Any proof on the transfer of ownership such as any of the following: Deed of sale or assignment or transfer of rights/ownership, Memorandum of Agreement, or notarized Affidavit of the owner, proprietor, Chairman or CEO of the establishment validating the transfer 3. Payment

Change of Business Name	
C	1. Change only in the business name 2. No transfer of location or change of ownership.
D	1. Application Form 2. Proof of business name registration reflecting the new name

Zonal Change in Address	
C	Shall refer to change of the name/number of the street/building without physical transfer of the establishment.
D	1. Application Form 2. Payment

Change of Qualified Personnel	
C	There is a change of the identified qualified person registered with FDA
D	1. Application Form 2. Payment

Deletion of Activity	
C	Shall refer to deletion of any approved/added activity.
D	1. Application Form 2. Payment

* C - Condition
** D - Documentary Requirements

CERTIFIED TRUE C

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

12 AUG 2016

FDA CIRCULAR
No. 2016-014

TO : **ALL MANUFACTURERS/ EXPORTERS/ IMPORTERS/ DISTRIBUTORS/ TRADERS OF PREPACKAGED PROCESSED FOOD PRODUCTS AND OTHERS CONCERNED**

SUBJECT : **Procedure for the Use of Electronic Registration (E-Registration) System for Prepackaged Processed Food Products**

I. BACKGROUND

Pursuant to Paragraph (n), Section 2, Article II (A), Book I of the Rules Implementing Republic Act No. 9711, otherwise known as the *Food and Drug Administration (FDA) Act of 2009*, Section VI Item F of Administrative Order No. 2014-0029, *Rules and Regulations on Licensing of Establishments and Registration of Processed Food Products, and Other Food Products, and for Other Purposes*, and consistent with the objective of Republic Act No. 8792 or the *Electronic Commerce Act of 2000* in promoting the universal use of electronic transaction in the government and general public, the FDA issued the FDA Circular No. 2014-029 or the *"Procedure for the Use of Electronic Registration (E-Registration) System for Raw Materials or Ingredients and Low Risk Pre-Packaged Processed Food Products"* on 28 November 2014 which implemented an electronic registration (E-registration) system initially applicable for raw materials or ingredients and low risk prepackaged processed food products in order to streamline the application and evaluation process.

In the interest of consistent, effective and efficient public service delivery, the electronic registration system shall hereby include medium and high risk food products to cover all processed food products; thus, the promulgation of this Circular.

II. GUIDELINES

A. General Guidelines

1. The Electronic Registration (E-Registration) system shall cover the registration of raw materials or ingredients, low risk, medium risk and high risk pre-packaged processed food products.

2. The risk classification of food products shall follow the list found in Annex A of Administrative Order No. 2014-0029 (Please see Annex A). The list is not limited to Annex A but may be expanded to cover other food products as may be required by FDA.

3. The validity period of Certificate of Product Registration (CPR) applications filed through the E-Registration shall be based on existing FDA rules and regulations.

4. The fees and charges for all applications filed through the E-Registration shall be based on the current prescribed fees as implemented by the FDA.

5. Food establishments with multiple manufacturing plants producing the same product shall file one (1) CPR per product per plant for the purpose of traceability and consistency in the E-Registration database.

6. Food Establishments with License-to-Operate activity as Importer, Trader and Manufacturer shall be regarded as the Market Authorization Holder (MAH). For the purposes of E-Registration, the MAH shall be primarily responsible for the filing and securing of CPR applications, ensuring safety and continuing compliance of the product with applicable rules and regulations of FDA.

7. Representative samples of food supplements submitted to FDA should be properly labelled with clear and complete information.

8. All certificates of analyses submitted must be issued within six (6) months from the date of filing of the application.

B. Specific Guidelines

1. Using the E-Registration system, the initial registration shall require the encoding of all the product information for every product application and submission of all labels and supporting documents.

2. For approved product applications filed through the E-registration system, the Company E-registration Account Holder may apply for Renewal, Amendment, Re-Issuance or Cancellation of their respective products through the E-Registration portal. The account holder shall be the authorized representative of the MAH.

3. Succeeding amendments of food products approved through the E-Registration system shall cover the following changes :

   a. Change in/Additional Commercial Presentation (i.e. Packaging Size)
   b. Change in/Additional Packaging Type or Packaging Material
   c. Change in/Additional Packaging Design
   d. Change/Extension in Shelf-Life (applicable only to previously issued CPRs of Food Supplements reflecting shelf-life)
   e. Change in Brand Name
   f. Change in Product Name
   g. Change in Business/Company Name
   h. Change in Business/Company Address
   i. Exportation of Previously Registered Product Initially for Local Distribution
   j. Transfer of Ownership of a Registered Product
   k. Change in/ Additional Supplier
   l. Other cases as declared in succeeding FDA issuances

4. Applications for Renewal without changes from the previously approved product information and label shall be automatically renewed upon application.

5. Should a product fail to meet the requirements for product registration, applicable product standards and labeling regulations, a Letter of Denial shall be electronically issued to the inbox of the respective user account of the applicant. The applicant shall be given a maximum of six (6) months to comply and file for re-application. Any application submitted thereafter shall be considered as initial application.

6. For medium and high risk food products with standard of identity (e.g. Infant Formula, Milk Supplement, Foods for Infants and Young Children, Foods for Special Medical Purposes, Foods for Special Dietary Uses, food supplements, bottled water, etc.), the corresponding Certificates of Analysis for assessment of compliance to such standard must be uploaded.

7. For food products covered by Republic Act No. 8172 or the *"An Act for Salt Iodization Nationwide (ASIN)"* and Republic Act No. 8976 or otherwise known as the *"Philippine Food Fortification Act of 2000"*, the Certificate of Analysis to attest conformity to the fortification levels must be uploaded.

8. For Food Supplements (FS), the Physical, Chemical and Microbiological Analysis, Stability Data of the finished product and Safety Data (e.g. LD50 or toxicity tests as applicable to products with herbs and botanical ingredients not included in Official Pharmacopoeias and Generally Recognized as Safe (GRAS) list or other applicable test procedures or reports to assess potential toxicity) must be attached to address uncertainties on safety of the product.

9. Nutrition and health claims declared on the product labels must be supported by relevant documents (e.g. scientific researches, etc.) following Bureau Circular 2007-002 *(Guidelines on the Use of Nutrition and Health Claims in Food).*

C. Procedural Guidelines

1. Issuance of a CFRR E-Registration User Account

   a. The CFRR E-Registration User Account and Password is company-specific. An officer/representative handling multiple companies shall secure a separate user account and password for each respective company.

   b. The applicant shall be assigned an FDA account in order to apply through e-registration. The applicant shall secure a notarized authorization letter from the company (with a valid License-to-Operate Number) being represented (Annex B) or the company account holder. He/She shall send a request for a User Account to **info@fda.gov.ph** following the format specified below with the scanned notarized authorization letter.

SUBJECT:	CFRR: E-Registration
BODY:	Email Address:
	Last Name:
	First Name:
	Middle Name:
	Company Name:

c. The issued CFRR E-Registration User Account shall be sent to the e-mail provided in the request.

d. When there is a change of the representative of the applicant company, the applicant shall request for a change in credentials of the CFRR E-Registration User Account by sending an e-mail to info@fda.gov.ph with "**CFRR: E-registration**" as the subject and attaching a scanned copy of the Affidavit of Undertaking (**Annex C**).

2. Accomplishing E-Registration Applications

a. All information filled out by the applicant during the process shall be reflected in the final output (either CPR or Letter of Denial). Thus, it is imperative for the client to be careful and diligent in filling out all required information.

b. Fill out all necessary information in **ALL CAPS**, except for Trademark, Corporate De Facto (e.g. GmbH) and e-mail address.

c. A **MINIMUM** of three (3) contact information in the form of E-Mail, Telephone and Mobile Number must be declared.

d. Declare ALL ingredients in DESCENDING order of proportion. For multi-component ingredients (e.g. non-dairy creamer), indicate the phrase "as follows" in parenthesis after the ingredient and declare each specific component also in parenthesis.

e. In declaring the product specifications for physical, chemical, and microbiological parameters, ensure the completeness and accuracy of the details since these shall be verified later during Post-Market Surveillance (PMS).

f. In attaching Product Labels or other supporting documents (e.g. Certificates of Analyses, LD50, etc.) make sure that ALL information are reflected **CLEARLY** and **ACCURATELY**. Limit the total size of attachments to 20 MB with a limit of 2 MB per file using the format ".png" or ".pdf".

g. Product labels in commercial presentation should be scanned clearly reflecting all sides with complete information and shall be named following the format "Label_(Case Number)", e.g. "Label_36252.pdf" or " Label_36252.png".

3. Initial Application

a. Access the online portal through https://www.fda.gov.ph. Provide the company-specific Username and Password, and then click the **"CFRR**

Electronic Registration – Food Product Registration (Initial Application Form)".

b. Read carefully the **"DECLARATION"** before proceeding with the application process. The "**DECLARATION**" conveys a binding agreement between the applicant and the FDA to provide complete and accurate information, assuming full responsibility for the safety of the product being registered, with an undertaking to comply with all applicable rules and regulations. Clicking the "**Yes, I agree**" button shall continue the registration process. If the user fails to do so, access to proceed to E-Reg shall be denied.

c. After providing the required information, a system-generated Order of Payment shall be received. Make sure that all information are complete and correct before making any payment.

d. Pay the corresponding assessed fee through the FDA Main Office Alabang Cashier or BancNet online payment gateway following the procedure per FDA Advisory 2015-021 or any applicable payment system prescribed by the FDA.

e. For food supplements, one (1) representative sample in commercial presentation consistent with the e-registration application shall be labelled with the respective case number, packaged accordingly to protect the contents and submitted to the Food and Drug Administration Main Office Building within ten (10) days upon payment of assessed fee through either of the following means:

   i. Personal delivery to the Public Assistance, Information and Receiving (PAIR) Unit in the FDA Main Office Building; or

   ii. Delivery via registered courier that must contain the following information:

TO:	**FOOD AND DRUG ADMINISTRATION** **Civic Drive, Filinvest City, Alabang, Muntinlupa City 1781**
FROM:	**Company's complete name and address**
SUBJECT:	**Food Product E-Registration Application (Case No.)**

f. Track the application through the "**Process Map**" function of the system.

   i. If the application is denied, an electronic Letter of Denial shall be sent in the **Inbox** of the account holder. All applications which are not approved may file for re-application.

   ii. If the application is approved, the current task would be "**Releasing**". This shall prompt the applicant to claim the Certificate of Product Registration at the Releasing Section of FDA.

4. Re-application

   a. To apply for re-application, access the online portal through https://www.fda.gov.ph. Provide the company-specific Username and Password, and double click on the specific product in the **Inbox** folder.

   b. Select the type of application from the drop-down menu after the "Declaration".

   c. Attach documents (i.e. letter of justification or clarification, scanned compliant labels, etc.) complying with the causes of denial per the electronically-issued Letter of Denial.

   d. Proceed as in Section C (Procedural Guidelines), No. 3 (Initial Application), letters (c), (d) and (f).

5. Amendment/Renewal Application

   a. To apply for amendment or renewal, access the online portal through https://www.fda.gov.ph. Provide the company-specific Username and Password, and double click on the specific product in the **Inbox** folder.

   b. Select the type of application from the drop-down menu after the "Declaration".

   c. Provide the required information completely and accurately.

   d. Proceed as in Section C (Procedural Guidelines), No. 3 (Initial Application), letters (c), (d) and (f).

III. Transitory Provisions

A. The E-Registration shall be accessible for applications for registration of raw materials or ingredients, low risk, medium risk and high risk pre-packaged processed food products starting 15 August 2016.

B. Food products with Certificate of Product Registration (CPR) issued prior to the implementation of the E-Registration system that are due for renewal or with amendment/s and food product applications previously denied through the PAIR system shall apply through the E-Registration system by choosing "Renewal", "Amendment" and "Reapplication", respectively, on the General Information portion of the E-Registration application.

C. Existing labels printed with previously assigned FR Number shall be allowed to exhaust for a period of one year from the date of issuance of the new FR Number provided by the E-Registration system.

D. Applications for registration of medium risk and high risk prepackaged processed food products using the Integrated Application Form (IAF) shall still be accommodated by the Public Assistance and Information (PAIR) System until 31 September 2016.

IV. Repealing Clause

FDA Circular 2014-029 and other issuances inconsistent with this Circular are hereby repealed.

V. Separability Clause

If any provision of this Circular be declared as invalid or unenforceable, the validity and enforceability of the remaining portions or provisions shall remain in full force and effect.

VI. Penalty Clause

Administrative penalties and sanctions shall be applied accordingly as per Implementing Rules and Regulations of Republic Act No. 9711 (FDA Act of 2009) and Republic Act No. 10611 (Food Safety Act of 2013).

VII. Effectivity

Electronic registration of all pre-packaged processed food products shall take effect on 31 August 2016 following publication in two (2) newspapers of general circulation and submission to the University of the Philippines Office of the National Administrative Register (ONAR).

MARIA LOURDES C. SANTIAGO, MSc, MM
OIC, Director General

ANNEX A

Risk Classification of Food Products

Table 1. Low Risk (LR) Foods – Foods that are unlikely to contain pathogenic microorganisms and will not normally support their growth because of food characteristics and foods that are unlikely to contain harmful chemicals.

LOW RISK FOOD PRODUCTS
A. FATS, OILS AND FAT EMULSIONS 1. Butter oil, anhydrous milkfat, ghee 2. Vegetable oils and fats 3. Animal fats (lard, tallow, fish oil and other animal fats) 4. Fat emulsions mainly of type oil-in-water, including mixed and/or flavored products based on fat emulsion 5. Fat emulsions mainly of type water-in-oil (butter, fat spreads, margarine dairy fat spreads and blended spreads) 6. Fat-based desserts excluding dairy-based desserts
B. PROCESSED FRUITS, VEGETABLE AND EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) SEAWEEDS, AND NUTS AND SEEDS 1. Dehydrated fruits or vegetables, including candied fruits (mechanically dried) 2. Jams, jellies, marmalades (pastry, topping, filling, coconut spreads) 3. Dehydrated Vegetable protein products 4. Fruits or vegetables in vinegar, oil or brine 5. Fruit-based spreads (e.g. chutney) excluding jams, jellies and marmalades 6. Fruit preparations, including pulp, purees, fruit toppings and coconut milk 7. Cooked fruits 8. Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds 9. Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seedin pulps and preparations (e.g. vegetable desserts and sauces, candied vegetables) other than food in HR Letter B.8 (Vegetable purees, spreads – peanut butter) 10. Cooked or fried vegetables(including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds
C. CONFECTIONERY 1. Confectionery including hard and soft candy, nougats, marzipans, etc. other than in MR (cocoa products and chocolate products) 2. Chewing gum 3. Decorations (e.g. for fine bakery wares, sugar flowers), toppings (non-fruit), and sweet sauces
D. CEREAL-BASED PRODUCTS, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares in Letter F below 1. Flours, starches (including soybean powder) and flour mixes 2. Breakfast cereals including rolled oats 3. Pasta and noodles and like products (e.g. rice paper, rice vermicelli, soybean pastas and noodles) a. Fresh pastas and noodles and like products b. Dried pastas and noodles and like products c. Pre-cooked pastas and noodles and like products 4. Cereal and starch based desserts (e.g. rice pudding, tapioca pudding, native delicacies) 5. Batters (e.g. for breading or batters for fish or poultry) 6. Pre-cooked or processed rice products, including rice cakes (Oriental type only) 7. Soybean products (excluding soybean-based seasonings and condiments under LR Letter I (seasonings, condiments and sauces) a. Soybean-based beverages b. Soybean-based film

LOW RISK FOOD PRODUCTS
c. Soybean curd (tofu) d. Semi-dehydrated soybean curd 1) Thick gravy-stewed semi-dehydrated soybean curd 2) Deep fried semi-dehydrated soybean curd 3) Semi-dehydrated soybean curd, other than in LRD.7.d.1) and 7.d.2) e. Dehydrated soybean curd (kori tofu) f. Other soybean protein products
E. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME Edible casings (e.g. sausage casings)
F. BAKERY WARES AND BAKERY RELATED PRODUCTS 1. Bread and ordinary bakery wares and mixes a. Breads and rolls – yeast-leavened breads and specialty breads, soda breads b. Crackers, excluding sweet crackers c. Other ordinary bakery products (e.g. bagels, pita, English muffins) d. Bread-type products, including bread stuffing and bread crumbs e. Steamed bread and buns f. Mixes for bread and ordinary bakery wares 2. Fine bakery wares (sweet, salty or savory) and mixes Mixes for fine bakery wares (e.g. cakes, pancakes)
G. SWEETENERS, INCLUDING HONEY 1. Refined and raw sugars a. White sugar, dextrose anhydrous, dextrose monohydrate, fructose b. Powdered sugar, powdered dextrose c. Soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup, raw cane sugar i. Dried glucose syrup used to manufacture sugar confectionery ii. Glucose syrup used to manufacture sugar confectionery d. Lactose e. Plantation or mill white sugar 2. Brown sugar excluding products under LRG.1.c (soft white sugar, etc.) 3. Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products under G.1.c(soft white sugar, etc.) 4. Other sugars and syrups (e.g. xylose, maple syrup, sugar toppings), including coconut sugar 5. Honey 6. Table-top sweeteners, including those containing high-intensity sweeteners
I. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS 1. Salt and salt substitutes 2. Herbs, spices, seasonings and condiments (e.g. seasoning for instant noodles) 3. Vinegars 4. Mustards 5. Soups and broths Mixes for soups and broths 6. Sauces and like products a. Mixes for sauces and gravies b. Clear sauces (fish sauce) 7. Yeast and like products 8. Soybean-based seasonings and condiments a. Fermented soybean paste (e.g. miso) b. Soybean sauce 1) Fermented soybean sauce 2) Non-fermented soybean sauce 3) Other soybean sauce 9. Protein products other than from soybeans, marinades

LOW RISK FOOD PRODUCTS
J. BEVERAGES, excluding dairy products 1. Non-alcoholic ("soft") beverages Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages 2. Alcoholic beverages, including alcohol-free and low-alcoholic counterparts a. Beer and malt beverages b. Cider and perry c. Grape wines 1) Still grape wine 2) Sparkling and semi-sparkling grape wines 3) Fortified grape wine, grape liquor wine, and sweet grape wine d. Wines (other than grape) e. Mead f. Distilled spirituous beverages containing more than 15% alcohol g. Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)
K. READY-TO-EAT SAVOURIES 1. Snacks – potato-, cereal- or starch-based (from roots and tubers, pulses and legumes), including chips and crunchies 2. Chicharon 3. Snacks – fish-based

Table 2. Medium Risk (MR) Foods – Foods that may contain pathogenic micro-organisms but will not normally support their growth because of food characteristics; or food that is unlikely to contain pathogenic micro-organisms because of food type or processing, but may support the formation of toxins or the growth of pathogenic micro-organisms.

MEDIUM RISK FOOD PRODUCTS
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions 1. Condensed milk and analogues (plain) (evaporated/reconstituted milk) a. Condensed milk (plain) b. Beverage whiteners 2. Milk powder and cream powder and powder analogues (plain)
B. FROZEN DESSERTS 1. Non-Dairy based (e.g. sherbet, sorbet) 2. Edible ices – popsicles
C. PROCESSED FRUITS, VEGETABLE AND EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) SEAWEEDS, AND NUTS AND SEEDS 1. Tomato products 2. Frozen fruits 3. Canned or bottled (pasteurized) or retort pouch fruit and vegetable preserve in juice, syrup, brine 4. Fruit-based desserts, gelatin (including water-based fruit flavored desserts, i.e. gels) 5. Fermented fruit products 6. Fruit fillings for pastry 7. Fermented vegetable products (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products MR Letter E.1 and E.2 (fermented soybeans and fermented soybean curd) and LR Letters I.8.b. 1) to 3) (soybean sauces) 8. Vegetable protein products (canned and frozen)
D. CONFECTIONERY Cocoa products and Chocolate products including imitations and chocolate substitutes a. Cocoa mixes (powders) and cocoa mass/ cake b. Cocoa mixes (syrups) c. Cocoa-based spreads, including fillings d. Cocoa and chocolate products, including *"tablea"*; and imitation chocolate, chocolate substitute products
E. CEREAL-BASED PRODUCTS, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree – Soybean products 1. Fermented soybeans (e.g. natto, tempe)

2. Fermented Soybean curd

F. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME

1. Processed meat, poultry and game products in whole or cuts
   a. Non-heat treated processed meat, poultry and game products (cured, fermented, chilled)
      1) Cured (including salted) non-heat treated processed meat, poultry and game products
      2) Cured (including salted) and dried non-heat treated processed meat, poultry and game products
      3) Fermented non-heat treated processed meat, poultry and game products
2. Processed comminuted meat, poultry and game products
   a. Non-heat treated processed meat, poultry and game products (cured, fermented, chilled)
      1) Cured (including salted) non-heat treated processed meat, poultry and game products
      2) Cured (including salted) and dried non-heat treated processed meat, poultry and game products (jerky, shredded beef/ pork)
      3) Fermented non-heat treated processed meat, poultry and game products

H. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS

1. Processed fish and fish products, including molluscs, crustaceans and echinoderms
   a. Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans and echinoderms
2. Semi-preserved fish and fish products, including molluscs, crustaceans and echinoderms
   a. Fish and fish products, including molluscs, crustaceans and echinoderms – marinated and/or in jelly
   b. Fish and fish products, including molluscs, crustaceans and echinoderms – pickled and/or in brine
   c. Salmon substitutes, caviar and other fish roe products
   d. Semi-preserved fish and fish products, including molluscs, crustaceans and echinoderms (e.g. fish paste), excluding products under MR Letter H.2.a to c above

I. EGG AND EGG PRODUCTS

1. Preserved eggs, including alkaline, salted and canned eggs (salted eggs, century eggs)
2. Egg-based desserts (e.g. custard)

J. BAKERY WARES AND BAKERY RELATED PRODUCTS

Fine bakery wares (sweet, salty or savory) and mixes
   a. Cakes, cookies, pies, pastries, doughnuts, sweet rolls, scones, muffins, waffles – plain / without filling
   b. Frozen dough

K. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS

1. Soups and broths Ready-to-eat soups and broths, including canned, bottled and frozen
2. Sauces and like products
   a. Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dips)
   b. Non-emulsified sauces (ketchup, cheese sauce, cream sauce, brown gravy)
3. Salads (e.g. macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based, spreads under HR Letter B.8 (peanut butter)and MR D.1.c (cocoa-based spreads)

L. BEVERAGES, excluding dairy products

1. Non-alcoholic ("soft") beverages
   a. Fruit and vegetable juices - (fruit juice, vegetable juice, concentrates for fruit juice, concentrates for vegetable juice)
   b. Fruit and vegetable nectars (fruit nectar, vegetable nectar, concentrates for fruit nectar, concentrates for vegetable nectar)
   c. Water-based flavored drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks
      1) Carbonated water-based flavored drinks
      2) Non-carbonated water-based flavored drinks, including punches and ades
      3) Concentrates (liquid or solid) for water-based flavored drinks
   d. Powdered cocoa drink mixes (cocoa)

M. FOOD SUPPLEMENT/ HERBAL FOOD/ HERBAL DIETARY SUPPLEMENTS

1. Vitamins and minerals
2. Amino acids

N. READY-TO-EAT SAVOURIES

Processed nuts, including coated nuts and nut mixtures (with e.g. dried fruits)

Table 3. High Risk (HR) Food – foods that may contain pathogenic microorganisms and will support the formation of toxins or the growth of pathogenic microorganisms and foods that may contain harmful chemicals

HIGH RISK FOOD PRODUCTS
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions 1. Milk and dairy-based drinks a. Milk (plain) and buttermilk (plain) b. Dairy-based drinks, flavored and/or fermented (e.g. chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks) 2. Fermented and renneted milk products (plain), excluding dairy-based drinks in HR A.1.b a. Fermented milks (plain) 1) Fermented milk (plain), not heat-treated after fermentation 2) Fermented milks (plain), heat-treated after fermentation b. Renneted milk (plain) 3. Cream (plain) and the likes (cream analogs) a. Pasteurized cream (plain) b. Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain) c. Clotted cream (plain) d. Cream analogues 4. Cheese and analogs a. Unripened cheese b. Ripened cheese 1) Ripened cheese, includes rind 2) Rind of ripened cheese 3) Cheese powder (for reconstitution; e.g. for cheese sauces) c. Whey cheese d. Processed cheese 1) Plain processed cheese 2) Flavored processed cheese, including those containing fruits, vegetables, meat, etc e. Cheese analogues f. Whey protein cheese 5. Dairy-based desserts (e.g. pudding, fruit or flavored yoghurt) 6. Whey and whey products, excluding whey cheeses a. Liquid whey and why products b. Dried whey and whey products 7. Milk for manufacture 8. Dairy-based frozen desserts (e.g. ice cream)
B. PROCESSED FRUITS, VEGETABLES and EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds 1. Dried Fruits and vegetable – plain/ sun-dried (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds 2. Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed – purees, spreads (e.g. peanut butter)
D. CONFECTIONERY Chocolate with nuts
F. BAKERY WARES AND BAKERY RELATED PRODUCTS 1. Fine bakery products with fillings: meat, milk, poultry, cream, other perishable foods; icings; and coatings 2. Cookies with nuts
G. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME 1. Processed meat, poultry and game products in whole or cuts a. Heat-treated processed meat, poultry and game products (canned) b. Frozen processed meat, poultry and game products (marinated pork/ beef/ chicken cuts) 2. Processed comminuted meat, poultry and game products a. Heat-treated processed meat, poultry and game products (canned) b. Frozen processed meat, poultry and game products (nuggets, patties, dumplings, salami, meat loaf, hotdog)
H. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS 1. Processed fish and fish products, including molluscs, crustaceans and echinoderms a. Frozen fish, fish fillets and fish products, including molluscs, crustaceans and echinoderms b. Frozen battered fish, fish fillets and fish products, including molluscs, crustaceans and echinoderms;

including value added products (battered, marinated, smoked, spiced, fish and squid balls preparations) c. Frozen minced and creamed fish products, including molluscs, crustaceans and echinoderms d. Cooked and/or fried fish and fish products, including molluscs, crustaceans and echinoderms 1) Cooked fish and fish products 2) Cooked molluscs, crustaceans and echinoderms 3) Fried fish and fish products, including molluscs, crustaceans and echinoderms 2. Fully preserved, including canned or fermented fish and fish products, including molluscs, crustaceans and echinoderms
I. EGG AND EGG PRODUCTS Egg products a. Liquid egg products b. Frozen egg products (e.g. frozen eggs, frozen egg whites, frozen egg yolks) c. Dried and/or heat coagulated egg products (e.g. dried eggs, dried egg whites, dried egg yolks)
J. FOODSTUFFS INTENDED FOR PARTICULAR NUTRITIONAL USES 1. Infant formula, follow-on formula and formula for special medical purposes for infants 2. Complementary foods for infants and young children 3. Dietetic foods intended for special medical purposes (excluding products under HR Letter J.1) 4. Dietetic formula for slimming purposes and weight reduction 5. Dietetic foods (e.g. supplementary foods for dietary use) excluding products under HR Letter J.1 to 4 and Letter K, Food supplements) 6. Weaning foods for infants and growing children 7. Dietetic foods for special medical purpose 8. Dietetic formulas for weight control
J. BOTTLED WATER
K. FOOD SUPPLEMENT/ HERBAL FOOD/ HERBAL DIETARY SUPPLEMENTS 1. Herbs and botanicals 2. Products with other nutritional substances
L. NOVEL / NEW INNOVATIONS in FOOD New in the international or local market

ANNEX B

TEMPLATE
[[COMPANY LETTERHEAD]]

(DATE)

(NAME)
Director General
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

Attn: **(NAME)**
Director IV
Center for Food Regulation and Research

Sir/Madam:

In accordance with Republic Act No. 9711 and other related issuances, we, _____ (Company Name), with LTO number _____ issued on _____ valid until _____, hereby authorize _____ (Name of Representative) as the account holder for e-registration of processed food products and shall be responsible for all applications submitted through e-registration.

_____
(Owner/General Manager/President)

Subscribed and sworn to me this _____ day of _____ at _____.

_____
NOTARY PUBLIC

Doc No. _____
Page No. _____
Book No. _____
Series of _____

ANNEX C

TEMPLATE
[[COMPANY LETTERHEAD]]

AFFIDAVIT OF UNDERTAKING

I, _____ Filipino Citizen, of legal age, with residence address at _____, having been duly sworn to in accordance with the Law, do hereby certify that:

1. I am the President/General Manager of _____, with business address located at _____, a duly registered company with the Food and Drug Administration under LTO Number _____ issued on _____ valid until _____.

2. That I hereby appoint and authorize _____, of legal age, residing at _____ as the company's Regulatory Officer in replace of _____ whose name appears as representative in the E-Registration System of the Philippine Food and Drug Administration

3. That _____ is also hereby authorized to transact in behalf of the company for E-Registration concerns and matter.

Subscribed and sworn to me this _____ day of _____ at _____.

_____
NOTARY PUBLIC

Doc No. _____
Page No. _____
Book No. _____
Series of _____

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, Muntinlupa City

FDA CIRCULAR
NO. 2013-010

27 February 2013

TO: ALL CONCERNED

SUBJECT: **REVISED GUIDELINES FOR THE ASSESSMENT OF MICROBIOLOGICAL QUALITY OF PROCESSED FOODS**

As part of the mandate of the Food and Drug Administration to protect the public health and pursuant to the provisions of Republic Act No. 9711 otherwise known as the "Food and Drug Administration Act of 2009", the Bureau Circular No. 01-A s. 2004 *Guidelines for the Assessment of Microbiological Quality of Processed Food* is hereby revised with the following considerations: 1. Addition of new food category/products, 2. The need to update old references, 3. Adoption of approved CODEX Alimentarius Commission Guidelines.

This FDA Circular is hereby issued to serve as guidelines for the assessment of microbiological quality of certain processed foods; and help ensure that food manufacturers comply with Good Manufacturing Practices (GMP).

The reference criteria are prescribed in Tables 1-14. The tables contain a description of the food to which a criterion applies, the required test(s) or the microorganisms considered to be acceptable, marginally acceptable or critical, and the number of samples which should conform to the limits.

The methods used for the enumeration or detection of specified microorganisms shall be those that have been internationally established. Such methods, as well as the cited specifications were obtained from the following internationally recognized references:

1. FDA Bacteriological Analytical Manual published by the AOAC
2. Compendium of Analytical Methods of the Canadian Health Protection Branch
3. Compendium of Methods for the Microbiological Examination of Foods compiled by the American Public Health Association (APHA)
4. Specifications and Standards for Foods, Food Additives, etc., Japan External Trade Organization
5. Microorganisms in Foods by the International Commission on Microbiological Specifications for Foods (ICMSF)
6. Codex Alimentarius Commission Guidelines
7. International Standards Organization (ISO) Microbiological Methods
8. Australia New Zealand Food Authority (ANZFA)

This FDA Circular shall take effect immediately and supersede other regulations or guidelines inconsistent herewith.

KENNETH Y. HARTIGAN-GO, MD
Acting Director IV

TABLE 1. MILK AND DAIRY PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Milk Powders (e.g. whole, nonfat or filled milk, buttermilk, whey & whey protein concentrate) (intended for children more than 36 months of age and adults)	*Salmonella*/25g, normal routine	10	0	0	
	for high risk population	30	0	0	
	SPC/APC, cfu/g	5	2	$5x10^3$	$5x10^4$
	Enterobacteriaceae cfu/g	5	1	10	10^2
Sweetened Condensed Milk	[1]Coliforms, cfu/g	5	1	10	10^2
	Yeast and Molds Count, cfu/g	5	1	10	10^2
	SPC/APC, cfu/g	5	1	10^3	10^4
Liquid Milk (evaporated or ready to drink) **& Cream** (UHT/sterilized)	Commercial Sterility	6	0	Commercially sterile	
Pasteurized Milk	[2]Coliforms, cfu/mL	5	1	10^2	10^3
	Salmonella/25mL	5	0	0	
	Listeria monocytogenes/25 mL	5	0	0	
	Psychrotrophic bacteria, cfu/mL	5	1	10	10^2
	SPC/APC, cfu/mL	5	1	$5x10^4$	10^5
	➢ for flavored milk	5	2	$5x10^4$	10^6
Pasteurized Cream	[1]Coliforms, cfu/g	5	1	10^2	10^3
	Salmonella/25g	5	0	0	
	Listeria monocytogenes/25g	5	0	0	
	Psychrotrophic bacteria, cfu/g	5	1	10	10^2
	SPC/APC, cfu/g	5	1	$5x10^4$	10^5
Yogurt and other fermented milk	*S. aureus* (coagulase +), cfu/mL	5	2	10	10^2
	[1]Coliforms, cfu/mL	5	2	10	10^2
	Salmonella/25mL	5	0	0	
	Lactic Acid, cfu/mL (required minimum level: $\geq 10^6$)	-	-	-	-

[1] Coliforms must be negative for *E. coli*

Legend: **n** – number of sample units selected from a lot of food to be examined
m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP
M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage
c – maximum allowable number of defective or marginally acceptable units

TABLE 1. MILK AND DAIRY PRODUCTS cont.

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Cheese and Cheese Products; e.g. Cottage Cheese; Soft and Semi-soft cheese (moisture ≥39%, pH > 5)	*S. aureus (coagulase +), cfu/g*	5	2	10^2	10^3
	E.coli, MPN/g	5	1	11	110
	Coliforms, MPN/g	5	1	11	10^3
	Psychrotrophic bacteria, cfu/g	5	2	10^2	10^3
	Salmonella/25g	5	0	0	
	Listeria monocytogenes/25g	5	0	0	
Processed Cheese Spread	[1]Coliforms, cfu/g	5	1	10	10^2
	S. aureus (coagulase +), cfu/g	5	1	10	10^2
	SPC/APC, cfu/g	5	2	10^4	$5x10^4$
All Raw Milk Cheese; Raw Milk Un-ripened cheese w/moisture>50%, pH > 5.0	*Campylobacter/25g*	5	0	0	
	Salmonella/25g	5	0	0	
	Listeria monocytogenes/25g	5	0	0	
	S. aureus (coagulase +), cfu/g	5	2	10^2	10^3

[1] Coliforms must be negative for *E. coli*

TABLE 2. FATS, OILS AND FAT EMULSIONS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Butter (whipped, pasteurized)	Enterococci, cfu/g	5	1	10	10^2
	YMC, cfu/g	5	1	20	10^2
	Proteolytic bacteria, cfu/g	5	1	10^2	10^3
	Coliforms, cfu/g	5	1	10	10^2
	S. aureus (coagulase +), cfu/g	5	0	10^2	
	Psychrotrophic bacteria, cfu/g	5	1	10	10^2
	SPC/APC, cfu/mL	5	1	$5x10^4$	10^5
Butter made from unpasteurized milk or milk products	Coliforms, cfu/g	5	1	10	10^2
	E.coli, MPN/g	5	1	3	11
	S. aureus (coagulase +), cfu/g	5	1	10	10^2
	Salmonella/25g	5	0	0	
	Listeria monocytogenes/25g	5	0	0	
	SPC/APC, cfu/g	5	1	$5x10^4$	10^5
Margarine	*S. aureus* (coagulase +), cfu/g	5	0	10	
	Faecal Coliform, MPN/g	5	2	50	$5x10^2$
	Listeria monocytogenes/25g	5	0	0	
	Salmonella/25g	5	0	0	
	SPC/APC, cfu/g	5	2	$2.5x10^4$	$2.5x10^5$
	YMC, cfu/g	5	2	50	$5x10^2$

Legend: **n** – number of sample units selected from a lot of food to be examined
m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP
M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage
c – maximum allowable number of defective or marginally acceptable units

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TABLE 3. EDIBLE ICES, INCLUDING SHERBET AND SORBET

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Ice Cream & Sherbet (plain and flavored)	[1]Coliforms, cfu/g	5	1	10	10^3
	Listeria monocytogenes/25g	5	0	0	
	Salmonella/25g	5	0	0	
	SPC/APC, cfu/g	5	2	10^4	$5x10^4$
	S. aureus (coagulase +), cfu/g	5	1	10	10^2
Ice Cream with added ingredients (nuts, fruits, cocoa etc.)	[1]Coliforms, cfu/g	5	2	10	10^3
	S. aureus (coagulase +), cfu/g	5	1	10	10^2
	Salmonella/25g	5	0	0	
	SPC/APC, cfu/g	5	2	$5x10^4$	$2x10^5$
	Listeria monocytogenes/25g	5	0	0	
Flavored Ice (e.g. Ice candy)	SPC/APC, cfu/g	5	2	10^2	10^4
	Coliforms, MPN/g	5	0	3.0	
	YMC, cfu/g	5	0	10^2	
	Salmonella /25g	5	0	0	

[1] Coliforms must be negative for *E. coli*

TABLE 4. CONFECTIONERIES

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Cocoa Powder	Molds, cfu/g	5	2	10^2	10^4
	Salmonella/ 25g	5	0	0	
	Coliforms, MPN/g	5	2	1.8	10
	SPC/APC, cfu/g	5	2	10^4	10^6
Chocolate Products	Molds, cfu/g	5	2	10^2	10^4
	Salmonella/ 25g	10	0	0	
	Coliforms, MPN/g	5	2	1.8	10^2
	SPC/APC, cfu/g	5	2	10^4	10^6
Chocolate Confectionaries (chocolate bars, blocks, bonbons)	Molds, cfu/g	5	2	10^2	10^3
	Salmonella/ 25g	5	0	0	
	Coliforms, MPN/g	5	2	1.8	10^2
	SPC/APC, cfu/g	5	2	10^3	10^6
Sugar Confectionaries (Hard and soft candies, toffees, caramel, fondants, creams, nougats and pastes)	Molds, cfu/g	5	2	10	10^2
	Salmonella/ 25g	5	0	0	
	Coliforms, MPN/g	5	2	1.8	10^2
	SPC/APC, cfu/g	5	2	10^4	10^6

Legend: n – number of sample units selected from a lot of food to be examined
m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP
M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage
c – maximum allowable number of defective or marginally acceptable units

TABLE 5. FRUITS AND VEGETABLES, NUTS AND SEEDS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Frozen Vegetables & Fruits (pH >4.5)	*E.coli*, MPN/g	5	2	110	10^3
Fermented Vegetables, Ready to Eat (e.g. Kimchi)	YMC, cfu/g	5	2	10^2	10^4
	Coliforms, MPN/g	5	0	3	
	E.coli, MPN/g	5	0	3	
	Salmonella /25g	5	0	0	
	Staphylococcus aureus, cfu/g	5	0	10	
Fruits & Vegetable products in Hermetically sealed containers (thermally processed)	Commercial sterility	6	0	Commercially sterile	
Dried Vegetables	*E. coli*, MPN/g	5	2	110	10^3
Coconut (desiccated)	Refer to PNS/BAFPS 25:2007				
Peanut Butter & other Nut Butters ➢ **consumed without heating or other treatment to destroy microbes**	*Salmonella*/ 25g	10	0	0	
➢ **used as ingredient in high moisture food**	*Salmonella*/ 25g	20	0	0	
Sun Dried Fruits	Molds, cfu/g	5	2	10^2	10^4
	Osmophilic Yeasts, cfu/g	5	2	10	10^3
	E.coli, MPN/g	5	2	3	11

[1]Coliforms must be negative for *E.coli*

TABLE 6. EGG AND EGG PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Pasteurized Egg Products (liquid, frozen or dried)	Coliforms, cfu/g	5	2	10	10^3
	Salmonella/25g	10	0	0	
	YMC, cfu/g (for dried products)	5	0	10	
	SPC/APC, cfu/g	5	0	$2.5x10^4$	10^5

Legend: **n –** number of sample units selected from a lot of food to be examined
m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP
M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage
c – maximum allowable number of defective or marginally acceptable units

TABLE 7. CEREALS AND CEREAL PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Breakfast Cereals	Molds, cfu/g	5	2	10	10^3
	Yeast & Yeastllike fungi, cfu/g	5	2	10	10^2
	Coliform, cfu/g	5	2	10	10^2
	SPC/APC, cfu/g	5	2	10^3	10^4
Cereals/Cereal Grains	YMC, cfu/g	5	2	10^2	10^4
	SPC/APC, cfu/g	5	2	10^2	10^6
	Coliform, cfu/g	5	2	10^2	10^4
	E.coli, MPN/g	5	2	10^2	10^4
Cultured seeds and grains (e.g. bean sprouts, alfalfa etc.)	*E. coli*, MPN/g	5	2	10	10^2
	Coliforms, cfu/g	5	2	10^2	10^4
	Salmonella/25g	5	0	0	
Soya Flours, Concentrates and Isolates	Molds, cfu/g	5	2	10^3	10^5
	Salmonella/25g	5	0	0	
Flour, Corn meal, Corn grits, Semolina	Molds, cfu/g	5	2	10^2	10^4
	Yeast & Yeastllike fungi, cfu/g	5	2	10	10^2
	Coliform, cfu/g	5	2	10	10^2
	Bacillus subtilis, cfu/g "rope spores"	5	2	10	10^2
Frozen entrees containing Rice or Corn Flour as main ingredient	*B. cereus*, cfu/g	5	1	10^2	10^4
Soy Protein	Coliforms, cfu/g	5	2	10^2	10^3
	E. coli, MPN/g	5	1	10	10^2
	Psychrotrophic bacteria, cfu/g	5	2	10^2	10^4
	Clostridium perfringens, cfu/g	5	2	10	10^2
	YMC, cfu/g	5	2	10	10^2
	Salmonella / 25g	5	0	0	
	SPC/APC, cfu/g	5	2	10^2	10^5
Tofu	*B. cereus*, cfu/g	5	2	10^2	10^3
	E. coli, MPN/g	5	0	1.8	
	S. aureus (coagulase +), cfu/g	5	2	10^2	10^3
Pasta Products and Noodles Uncooked (wet & dry)	Coliforms, cfu/g	5	2	10	10^3
	YMC, cfu/g	5	2	10^2	10^5
	S. aureus (coagulase +), cfu/g	5	1	10^2	10^4
	Salmonella / 25g	5	0	0	
	SPC/APC, cfu/g	5	2	10^3	10^5
Starch	Coliforms, cfu/g	5	2	10	10^2
	YMC, cfu/g	5	2	10^2	10^3
	Salmonella/25g	5	0	0	
	SPC/APC, cfu/g	5	2	10^3	$5x10^4$

Legend: **n –** number of sample units selected from a lot of food to be examined
m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP
M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage
c – maximum allowable number of defective or marginally acceptable units

TABLE 8. BAKERY PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Frozen Bakery products (ready to eat) with low-acid or high a_w fillings or toppings	*S. aureus* (coagulase +), cfu/g *Salmonella*/ 25g	5 5	1 0	10^2 0	10^4
Frozen Bakery Products (to be cooked) with low-acid or high a_w fillings or toppings (e.g. meat pies, pizzas)	*S. aureus* (coagulase +), cfu/g *Salmonella*/ 25g	5 5	1 0	10^2 0	10^4
Frozen and Refrigerated Doughs (Chemically leavened)	Molds, cfu/g Yeasts & Yeastlike Fungi, cfu/g Coliforms, cfu/g Psychrotrophic bacteria, cfu/g SPC/APC, cfu/g *Salmonella*/ 25g *S. aureus* (coagulase +) , cfu/g *E. coli*, MPN/g	5 5 5 5 5 5 5 5	2 2 2 2 2 0 2 0	10^2 10^5 10 10 10^2 0 10^2 3.0	10^4 10^6 10^2 10^3 10^7 10^4
Frozen & Refrigerated Doughs	Molds, cfu/g Yeasts & Yeastlike Fungi, cfu/g Coliforms, cfu/g Psychrotrophic bacteria, cfu/g SPC/APC, cfu/g	5 5 5 5 5	2 2 2 2 2	10^2 10^5 10 10 10^3	10^4 10^6 10^2 10^3 10^6
Baked Goods (microbiologically sensitive types e.g containing eggs & dairy products)	*S. aureus* (coagulase +), cfu/g MYC, cfu/g SPC/APC, cfu/g Coliforms, cfu/g	5 5 5 5	2 2 2 2	10^2 10^2 10^4 50	10^4 10^4 10^6 10^3
Coated or Filled, Dried Shelf-Stable Biscuits	[1]*Coliforms, MPN/g* *Salmonella/25g*	5 10	2 0	3 0	20

[1]Coliforms must be negative for *E.coli*

TABLE 9. READY TO EAT SAVOURIES

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Snack Foods	Molds, cfu/g Yeast & Yeastllike fungi, cfu/g Coliform, cfu/g SPC/APC, cfu/g	5 5 5 5	2 2 2 2	10 10 10 10^3	10^3 10^2 10^2 10^4

Legend: n – number of sample units selected from a lot of food to be examined
m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP
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TABLE 10. MEAT AND MEAT PRODUCTS**

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Dried Animal Products	*S. aureus* (coagulase +), cfu/g	5	1	10^2	10^4
	Clostridium perfringens, cfu/g	5	1	10^2	10^4
	Salmonella/25g	10	0	0	
Meat Paste & Paté (heat treated)	*Salmonella*/25g	5	0	0	
	Clostridium perfringens, cfu/g	5	2	10^2	10^3
	S. aureus (coagulase +), cfu/g	5	2	10^2	10^3
	[1]Coliforms, cfu/g	5	2	10	10^2
	SPC/APC, cfu/g	5	2	10^4	10^5
Cold Cuts, Frozen & Chilled Hot Dogs, Corned Beef, Luncheon Meat	*E.coli*, MPN/g	5	0	1.8	
	Salmonella/25g	10	0	0	
	S. aureus (coagulase +), cfu/g	5	2	10^2	10^3
	SPC/APC, cfu/g	5	2	10^5	10^6
Packaged cooked cured/salted meat (ham, bacon)	*S. aureus* (coagulase +), cfu/g	5	2	10^2	10^3
	Salmonella/25g	5	0	0	
	Listeria monocytogenes/25g	5	0	0	
Fermented, comminuted meat, not cooked (dry & semi-dry fermented sausages)	*E.coli*, MPN/g	5	0	1.8	
	S. aureus (coagulase +), cfu/g	5	1	10^3	10^4
	Salmonella/25g	5	0	0	
Cooked Poultry Meat, Frozen to be reheated before eating (e.g. prepared frozen meals)	*S. aureus* (coagulase +), cfu/g	5	1	10^3	10^4
	Salmonella/25g	5	0	0	
Cured/Smoked Poultry Meat	*S. aureus* (coagulase +), cfu/g	10	1	10^3	10^4
	Salmonella/25g	10	0	0	
Dehydrated Poultry Products	*Salmonella*/ 25g	10	0	0	
Fresh/Frozen Raw Chicken (during processing)	SPC/APC, cfu/g (at 20°C)	5	3	$5x10^5$	10^7
Meat Products in hermetically sealed containers	Commercial sterility	6	0	Commercially sterile	

[1]Coliforms must be negative for *E.coli*

** Effective 16 February 2010, all meat and meat products are being handled and regulated by the National Meat Inspection Service (NMIS) of the Department of Agriculture as mandated by RA 9296 "Meat Inspection Code of the Philippines and DA-DOH joint Administrative Order No.1 s 2009". Any guidelines set by the NMIS shall supersede the specifications herein stated once it is made available.

Legend: **n** – number of sample units selected from a lot of food to be examined
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TABLE 11. FISH AND FISH PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Fresh Frozen Fish[a] and Cold-Smoked[b]	*E.coli*, MPN/g	5	3	11	500
	S. aureus (coagulase +), cfu/g	5	2	10^3	10^4
	V. parahaemolyticus, cfu/g	5	2	10^2	10^3
	Salmonella/25g	5	0	0	
	SPC/APC, cfu/g	5	3	$5x10^5$	10^7
Pre-Cooked Breaded Fish	*E.coli*, MPN/g	5	2	11	500
	S. aureus (coagulase +), cfu/g	5	1	10^3	10^4
	SPC/APC, cfu/g	5	2	$5x10^5$	10^7
Frozen Raw Crustaceans[c]	*E. coli*, MPN/g	5	3	11	500
	S. aureus (coagulase +), cfu/g	5	2	10^3	10^4
	Salmonella /25g	5	0	0	
	V. parahaemolyticus, cfu/g	5	1	10^2	10^3
	SPC/APC, cfu/g	5	3	10^6	10^7
Frozen Cooked Crustaceans	*E. coli*, MPN/g	5	2	11	500
	S. aureus (coagulase +), cfu/g	5	0	10^2	
	Salmonella /25g	20	0	0	
	V. parahaemolyticus, cfu/g	10	1	10^2	10^3
	SPC/APC, cfu/g	5	2	$5x10^5$	$5x10^6$
Cooked, Chilled & Frozen Crabmeat[d]	*E. coli*, MPN/g	5	1	11	500
	S. aureus (coagulase +), cfu/g	5	0	10^3	
	V. parahaemolyticus, cfu/g	10	1	10^2	10^3
	SPC/APC, cfu/g	5	2	10^5	10^6
Fresh & Frozen Bivalve Molluscs[e]	*E. coli*, MPN/g	5	0	16	
	Salmonella/25g	20	0	0	
	V. parahaemolyticus, cfu/g	10	1	10^2	10^3
	SPC/APC, cfu/g	5	0	$5x10^5$	
Fish & Shellfish products in hermetically sealed containers (thermally processed)	Commercial Sterility	6	0	Commercially sterile	

[a] For fish derived from inshore/inland waters of doubtful bacteriological quality, particularly warm areas or harvested during summer. Tests for *Salmonella* and *V. parahaemolyticus* recommended if fish is to be eaten raw.

[b] Test for *S. aureus* recommended for smoked fish.

[c] Test for *S. aureus* recommended for breaded products. *Salmonella* and *V. parahaemolyticus* applied to products from waters or harvested during summer.

[d] SPC/APC for frozen products only

[e] Criteria to be used only for molluscs from approved harvesting areas where waters are free from enteric bacteria or virus contamination and no significant contamination by toxic metals or chemicals may be accumulated by animals
Tests for *Salmonella* and *V. parahaemolyticus* recommended for molluscs from endemic areas or harvested from warm waters during summer.

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TABLE 12. SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Dry Mixes for Soup and Sauces	*Clostridium perfringens, cfu/g*	5	2	10^2	10^3
	YMC, cfu/g	5	3	10^2	10^4
	Coliforms, cfu/g	5	3	10	10^3
	SPC/APC, cfu/g	5	2	10^4	10^6
	Salmonella/25g	5	0	0	
Yeast	*Salmonella/25g*	20	0	0	
Spices	*Molds, cfu/g*	5	2	10^2	10^4
	SPC/APC, cfu/g	5	2	10^4	10^6
Spices (ready to eat)	[1]*Coliforms, cfu/g*	5	2	10^2	10^3
	S. aureus (coagulase +), cfu/g	5	2	10^2	10^4
	Salmonella/ 25g	5	0	0	
	Molds, cfu/g	5	2	10^2	10^4
	SPC/APC, cfu/g	5	2	10^4	10^6
Salad Dressing, pH ≤ 4.6 (e.g. Mayonnaise, Thousand Island, Ranch, French)	*SPC/APC, cfu/g*	5	2	10	10^2
	YMC, cfu/g	5	2	10	10^2
	Salmonella/25g	5	0	0	
	Listeria monocytogenes/25g	5	0	0	

[1]Coliforms must be negative for *E.coli*

TABLE 13. BEVERAGES

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Non Alcoholic Beverages (e.g. Ready to drink, softdrinks, iced tea, energy drinks)	YMC, cfu/mL	5	0	1	
	Coliforms, cfu/mL	5	0	1	
	SPC/APC, cfu/mL	5	1	10	10^2
Frozen Juice Concentrate	SPC/APC, cfu/mL	5	2	10^2	10^5
	YMC, cfu/mL	5	1	10	50
Powdered Beverages (e.g. iced tea, powdered juices/mixes)	SPC/APC, cfu/g	5	0	$3x10^3$	
	Coliforms, cfu/g	5	0	10	

Legend: n – number of sample units selected from a lot of food to be examined
m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP
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TABLE 14. FOOD FOR INFANTS AND YOUNG CHILDREN

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Powdered Infant Formula with or without added Lactic acid producing cultures (intended for 0 to 6 months old)	Routine analysis: *Cronobacter spp.* / 10g **Salmonella* / 25 g For complaint investigation (additional to routine analysis): [1]Coliforms, MPN/g *E. coli,* MPN/g [2]Process Hygiene Indicators: SPC/APC, cfu/g Enterobacteriaceae/ 10g	 30 60 5 10 5 10	 0 0 2 1 2 2	 0 0 3 1.8 $5x10^2$ 0	 11 10 $5x10^3$ [3]NA
Follow-up Formula/Milk Supplement (intended for infants 6 months on and for young children 12-36 months of age)	Routine analysis: **Salmonella* / 25 g For complaint investigation (additional to routine analysis): [1]Coliforms, MPN/g *E. coli,* MPN/g [2]Process Hygiene Indicators: SPC/APC, cfu/g Enterobacteriaceae/ 10g	 60 5 10 5 10	 0 2 1 2 2	 0 3 1.8 $5x10^2$ 0	 11 10 $5x10^3$ [3]NA
Infant Formula - liquid (UHT/sterilized)	Commercial Sterility	6	0	Commercially Sterile	
Baby foods in hermetically sealed containers	Commercial Sterility	6	0	Commercially Sterile	
Dried and Instant products requiring reconstitution	[1]Coliforms, MPN/g SPC/APC, cfu/g **Salmonella* /25g *Listeria monocytogenes*/25g	5 5 60 5	1 2 0 0	3 10^3 0 0	20 10^4
Dried products requiring reconstitution and boiling before consumption	[1]Coliforms, cfu/g *Salmonella*/25g SPC/APC, cfu/g	5 5 5	2 0 3	10 0 10^4	10^2 10^5
Cereal based foods for infants	*Bacillus cereus,* cfu/g *Clostridium perfringens*, cfu/g SPC/APC, cfu/g *Salmonella*/25 g Coliforms, MPN/g	10 5 5 10 5	1 1 2 0 2	10^2 10 10^3 0 3	10^4 10^2 10^4 20

[1] Coliforms must be negative for *E. coli*

*25g sample units may be composited to a quantity not to exceed 400g
n = 60 → 4 x 15 (25g) composite units

[2] Process hygiene criteria to be applied to the finished product (powder form) or at any other previous point that provides the information necessary for the purpose of verification. The criteria is intended to be used by the manufacturer as a means of ongoing assessment of their hygiene programs. (CAC/RCP 66-2008)

[3] NA = not applicable

Legend: **n – number of sample units selected from a lot of food to be examined**
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GUIDELINES FOR USE OF NUTRITION AND HEALTH CLAIMS

CAC/GL 23-1997

Nutrition claims should be consistent with national nutrition policy and support that policy. Only nutrition claims that support national nutrition policy should be allowed.

Health claims should be consistent with national health policy, including nutrition policy, and support such policies where applicable. Health claims should be supported by a sound and sufficient body of scientific evidence to substantiate the claim, provide truthful and non-misleading information to aid consumers in choosing healthful diets and be supported by specific consumer education. The impact of health claims on consumers' eating behaviours and dietary patterns should be monitored, in general, by competent authorities. Claims of the type described in section 3.4 of the Codex *General Guidelines on Claims* are prohibited.

1. SCOPE

1.1 These guidelines relate to the use of nutrition and health claims in food labelling and, where required by the authorities having jurisdiction, in advertising[1].

1.2 These guidelines apply to all foods for which nutrition and health claims are made without prejudice to specific provisions under Codex standards or Guidelines relating to Foods for Special Dietary Uses and Foods for Special Medical Purposes.

1.3 These guidelines are intended to supplement the Codex *General Guidelines on Claims* and do not supersede any prohibitions contained therein.

1.4 Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.

2. DEFINITIONS

2.1 ***Nutrition claim*** means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. The following do not constitute nutrition claims:
(a) the mention of substances in the list of ingredients;
(b) the mention of nutrients as a mandatory part of nutrition labelling;
(c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.

2.1.1 ***Nutrient content claim*** is a nutrition claim that describes the level of a nutrient contained in a food.
(Examples: "source of calcium"; "high in fibre and low in fat".)

2.1.2 ***Nutrient comparative claim*** is a claim that compares the nutrient levels and/or energy value of two or more foods.
(Examples: "reduced"; "less than"; "fewer"; "increased"; "more than".)

2.1.3 ***Non-addition claim*** means any claim that an ingredient has not been added to a food, either directly or indirectly. The ingredient is one whose presence or addition is permitted in the food and which consumers would normally expect to find in the food.

2. 2 ***Health claim*** means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health. Health claims include the following:

[1] Advertising means any commercial communication to the public, by any means other than labelling, in order to promote directly or indirectly, the sale or intake of a food through the use of nutrition and health claims in relation to the food and its ingredients.

Adopted in 1997. Revised in 2004. Amended in 2001, 2008, 2009, 2010, 2011, 2012 and 2013. Annex adopted 2009.

2.2.1 ***Nutrient function claims*** – a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.

Example:

"Nutrient A (naming a physiological role of nutrient A in the body in the maintenance of health and promotion of normal growth and development). Food X is a source of/ high in nutrient A."

2.2.2 ***Other function claims*** – These claims concern specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

Examples:

"Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A."

2.2.3 ***Reduction of disease risk claims*** – Claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.

Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.

Examples:

"A healthful diet low in nutrient or substance A may reduce the risk of disease D.
Food X is low in nutrient or substance A."
"A healthful diet rich in nutrient or substance A may reduce the risk of disease D.
Food X is high in nutrient or substance A."

3. NUTRITION LABELLING

Any food for which a nutrition or health claim is made should be labelled with a nutrient declaration in accordance with Section 3 of the Codex *Guidelines on Nutrition Labelling*.

4. NUTRITION CLAIMS

4.1 The only nutrition claims permitted shall be those relating to energy, protein, carbohydrate, and fat and components thereof, fibre, sodium and vitamins and minerals for which Nutrient Reference Values (NRVs) have been laid down in the Codex *Guidelines for Nutrition Labelling*.

5. NUTRIENT CONTENT CLAIMS

5.1 When a nutrient content claim that is listed in the Table to these Guidelines or a synonymous claim is made, the conditions specified in the Table for that claim should apply.

5.2 A claim to the effect that a food is free of salt can be made, provided the food meets the conditions for free of sodium listed in the Table to these Guidelines.

5.3 Where a food is by its nature low in or free of the nutrient that is the subject of the claim, the term describing the level of the nutrient should not immediately precede the name of the food but should be in the form "a low (naming the nutrient) food" or "a (naming the nutrient)-free food".

Table of conditions for nutrient content claims

COMPONENT	CLAIM	CONDITIONS (not more than)
Energy	Low	40 kcal (170 kJ) per 100 g (solids) or 20 kcal (80 kJ) per 100 ml (liquids)
	Free	4 kcal per 100 ml (liquids)
Fat	Low	3 g per 100 g (solids) 1.5 g per 100 ml (liquids)
	Free	0.5 g per 100 g (solids) or 100 ml (liquids)
Saturated Fat[2]	Low	1.5 g per 100 g (solids) 0.75 g per 100 ml (liquids) and 10% of energy from saturated fat
	Free	0.1 g per 100 g (solids) 0.1 g per 100 ml (liquids)
Cholesterol[2]	Low	0.02 g per 100 g (solids) 0.01 g per 100 ml (liquids)
	Free	0.005 g per 100 g (solids) 0.005 g per 100 ml (liquids) and, for both claims, less than:1.5 g saturated fat per 100 g (solids) 0.75 g saturated fat per 100 ml (liquids) and 10% of energy from saturated fat
Sugars	Free	0.5 g per 100 g (solids) 0.5 g per 100 ml (liquids)
Sodium	Low	0.12 g per 100 g
	Very Low	0.04 g per 100 g
	Free	0.005 g per 100 g
COMPONENT	**CLAIM**	**CONDITIONS (not less than)**
Protein	Source	10% of NRV per 100 g (solids) 5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 10% of NRV per serving
	High	2 times the values for "source"
Vitamins and Minerals	Source	15% of NRV per 100 g (solids) 7.5% of NRV per100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 15% of NRV per serving
	High	2 times the value for "source"
Dietary Fibre	Source	3 g per 100 g[3] or 1.5 g per 100 kcal or 10 % of daily reference value per serving[4]
	High	6 g per 100 g[3] or 3 g per 100 kcal or 20 % of daily reference value per serving[4]

[2] In the case of the claims for saturated fat and cholesterol, trans fatty acids should be taken into account where applicable.
[3] Conditions for nutrient content claims for dietary fibre in liquid foods to be determined at national level.
[4] Serving size and daily reference value to be determined at national level.

6. COMPARATIVE CLAIMS

Comparative claims should be permitted subject to the following conditions and based on the food as sold, taking into account further preparation required for consumption according to the instructions for use on the label:

6.1 The foods being compared should be different versions of the same food or similar foods. The foods being compared should be clearly identified.

6.2 A statement of the amount of difference in the energy value or nutrient content should be given. The following information should appear in close proximity to the comparative claim:

6.2.1 The amount of difference related to the same quantity, expressed as a percentage, fraction, or an absolute amount. Full details of the comparison should be given.

6.2.2 The identity of the food(s) to which the food is being compared. The food(s) should be described in such a manner that it (they) can be readily identified by consumers.

6.3.1 For comparative claims about energy or macronutrients and sodium, the comparison should be based on a relative difference of at least 25% in the energy value or the nutrient content respectively between the compared foods and a minimum absolute difference in the energy value or nutrient content equivalent to the figure defined as "low" or as a "source" in the Table to these Guidelines.

6.3.2 For comparative claims about micronutrients other than sodium the comparison should be based on a difference of at least 10% of the NRV between the compared foods.

6.4 In addition to the conditions set out in Section 6.3, the content of trans fatty acids should not increase for foods carrying a comparison claim for decreased saturated fatty acids content.

6.5 The use of the word "light" or a synonymous claim should follow the criteria listed in Section 6.3 of these Guidelines and include an indication of the characteristics which make the food "light".

7. NON-ADDITION CLAIMS

7.1 Non-Addition of Sugars

Claims regarding the non-addition of sugars to a food may be made provided the following conditions are met.

(a) No sugars of any type have been added to the food (Examples: sucrose, glucose, honey, molasses, corn syrup, etc.);

(b) The food contains no ingredients that contain sugars as an ingredient (Examples: jams, jellies, sweetened chocolate, sweetened fruit pieces, etc.);

(c) The food contains no ingredients containing sugars that substitute for added sugars (Examples: non-reconstituted concentrated fruit juice, dried fruit paste, etc.); and

(d) The sugars content of the food itself has not been increased above the amount contributed by the ingredients by some other means (Example: the use of enzymes to hydrolyse starches to release sugars).

7.2 Non-Addition of Sodium Salts

Claims regarding the non-addition of sodium salts to a food, including "no added salt", may be made provided the following conditions are met[5].

(a) The food contains no added sodium salts, including but not limited to sodium chloride, sodium tripolyphosphate;

(b) The food contains no ingredients that contain added sodium salts, including but not limited to Worcestershire sauce, pickles, pepperoni, soya sauce, salted fish, fish sauce; and

(c) The food contains no ingredients that contain sodium salts that are used to substitute for added salt, including but not limited to seaweed.

[5] Competent authorities may permit the addition for technological purposes of sodium salts other than sodium chloride as long as the final food would still comply with the conditions for "low in sodium" claims as described in the Table to these Guidelines.

7.3 Additional Conditions

Additional conditions and/or disclaimer statements may be used with non-addition claims to assist consumer understanding of the claims within countries. Disclaimer statements should appear in close proximity to, on the same side and in the same prominence as the claim. These may be developed based on evidence of consumer use and understanding.

8. HEALTH CLAIMS

8.1 Health claims should be permitted provided that all of the following conditions are met:

8.1.1 Health claims must be based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of claimed effect and the relationship to health as recognized by generally accepted scientific review of the data and the scientific substantiation should be reviewed as new knowledge becomes available.[6] The health claim must consist of two parts:

1) Information on the physiological role of the nutrient or on an accepted diet-health relationship; followed by
2) Information on the composition of the product relevant to the physiological role of the nutrient or the accepted diet-health relationship unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food.

8.1.2 Any health claim must be accepted by or be acceptable to the competent authorities of the country where the product is sold.

8.1.3 The claimed benefit should arise from the consumption of a reasonable quantity of the food or food constituent in the context of a healthy diet.

8.1.4 If the claimed benefit is attributed to a constituent in the food, for which a Nutrient Reference value is established, the food in question should be:

(i) a source of or high in the constituent in the case where increased consumption is recommended; or,
(ii) low in, reduced in, or free of the constituent in the case where reduced consumption is recommended.

Where applicable, the conditions for nutrient content claims and comparative claims will be used to determine the levels for "high", "low", "reduced", and "free".

8.1.5 Only those essential nutrients for which a Nutrient Reference Value (NRV) has been established in the Codex *Guidelines on Nutrition Labelling* or those nutrients which are mentioned in officially recognized dietary guidelines of the national authority having jurisdiction, should be the subject of a nutrient function claim.

8.2 Health claims should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim, including the ability of competent national authorities to prohibit claims made for foods that contain nutrients or constituents in amounts that increase the risk of disease or an adverse health-related condition. The health claim should not be made if it encourages or condones excessive consumption of any food or disparages good dietary practice.

8.3 If the claimed effect is attributed to a constituent of the food, there must be a validated method to quantify the food constituent that forms the basis of the claim.

8.4 The following information should appear on the label or labelling of the food bearing health claims:

8.4.1 A statement of the quantity of any nutrient or other constituent of the food that is the subject of the claim.

8.4.2 The target group, if appropriate.

8.4.3 How to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources, where appropriate.

8.4.4 If appropriate, advice to vulnerable groups on how to use the food and to groups, if any, who need to avoid the food.

8.4.5 Maximum safe intake of the food or constituent where necessary.

8.4.6 How the food or food constituent fits within the context of the total diet.

8.4.7 A statement on the importance of maintaining a healthy diet.

[6] See Annex.

9. CLAIMS RELATED TO DIETARY GUIDELINES OR HEALTHY DIETS

Claims that relate to dietary guidelines or "healthy diets" should be permitted subject to the following conditions:

9.1 Only claims related to the pattern of eating contained in dietary guidelines officially recognized by the appropriate national authority.

9.2 Flexibility in the wording of claims is acceptable, provided the claims remain faithful to the pattern of eating outlined in the dietary guidelines.

9.3 Claims related to a "healthy diet" or any synonymous term are considered to be claims about the pattern of eating contained in dietary guidelines and should be consistent with the guidelines.

9.4 Foods which are described as part of a healthy diet, healthy balance, etc., should not be based on selective consideration of one or more aspects of the food. They should satisfy certain minimum criteria for other major nutrients related to dietary guidelines.

9.5 Foods should not be described as "healthy" or be represented in a manner that implies that a food in and of itself will impart health.

9.6 Foods may be described as part of a "healthy diet" provided that the label carries a statement relating the food to the pattern of eating described in the dietary guidelines.

ANNEX: RECOMMENDATIONS ON THE SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS[1]

1. SCOPE

1.1 These Recommendations are intended to assist competent national authorities in their evaluation of health claims in order to determine their acceptability for use by the industry. The recommendations focus on the criteria for substantiating a health claim and the general principles for the systematic review of the scientific evidence. The criteria and principles apply to the three types of health claims as defined in Section 2.2 of the Guidelines for use of nutrition and health claims.

1.2 These recommendations include consideration of safety in the evaluation of proposed health claims, but are not intended for the complete evaluation of the safety and the quality of a food, for which relevant provisions are laid out by other Codex Standards and Guidelines or general rules of existing national legislations.

2. DEFINITIONS

For the purposes of this Annex:

2.1 Food or food constituent refers to energy, nutrients, related substances, ingredients, and any other feature of a food, a whole food, or a category of foods on which the health claim is based. The category of food is included in the definition because the category itself may be assigned a common property of some of the individual foods making it up.

2.2 Health effect refers to a health outcome as defined in sections 2.2.1 to 2.2.3 of the Guidelines.

3. SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS

3.1. Process for the substantiation of health claims

The systematic review of the scientific evidence for health claims by competent national authorities takes into account the general principles for substantiation. Such a process typically includes the following steps:

(a) Identify the proposed relationship between the food or food constituent and the health effect;

(b) Identify appropriate valid measurements for the food or food constituent and for the health effect;

(c) Identify and categorise all the relevant scientific data;

(d) Assess the quality of and interpret each relevant scientific study;

(e) Evaluate the totality of the available relevant scientific data, weigh the evidence across studies and determine if, and under what circumstances, a claimed relationship is substantiated.

3.2. Criteria for the substantiation of health claims

3.2.1 The following criteria are applicable to the three types of health claims as defined in section 2.2 of the Guidelines for use of nutrition and health claims:

(a) Health claims should primarily be based on evidence provided by well-designed human intervention studies. Human observational studies are not generally sufficient *per se* to substantiate a health claim but where relevant they may contribute to the totality of evidence. Animal model studies, *ex vivo* or *in vitro* data may be provided as supporting knowledge base for the relationship between the food or food constituent and the health effect but cannot be considered as sufficient *per se* to substantiate any type of health claim.

(b) The totality of the evidence, including unpublished data where appropriate, should be identified and reviewed, including: evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous or unclear.

(c) Evidence based on human studies should demonstrate a consistent association between the food or food constituent and the health effect, with little or no evidence to the contrary.

3.2.2 Although a high quality of scientific evidence should always be maintained, substantiation may take into account specific situations and alternate processes, such as:

(a) 'Nutrient function' claims may be substantiated based on generally accepted authoritative statements by recognised expert scientific bodies that have been verified and validated over time.

(b) Some Health claims, such as those involving a relationship between a food category and a health effect, may be substantiated based on observational evidence such as epidemiological studies. Such studies should provide a consistent body of evidence from a number of well-designed studies. Evidence-based dietary guidelines and

[1] This document should be read in conjunction with the *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007)

authoritative statements prepared or endorsed by a competent authoritative body and meeting the same high scientific standards may also be used.

3.3. Consideration of the evidence

3.3.1 The scientific studies considered relevant for the substantiation of health claim are those addressing the relationship between the food or food constituent and the health effect. In case of a claimed health effect that cannot be measured directly, relevant validated biomarkers may be used (e.g. plasma cholesterol concentrations for cardiovascular disease risk).

3.3.2 The scientific data should provide adequate characterization of the food or food constituent considered as responsible for the health effect. Where applicable, the characterization includes a summary of the studies undertaken on production conditions, batch-to-batch variability, analytical procedures, results and conclusions of the stability studies, and the conclusions with respect to storage conditions and shelf-life.

3.3.3 The relevant data and rationale that the constituent for which the health claim is made is in a form that is available to be used by the human body should be provided where applicable. If absorption is not necessary to produce the claimed effect (e.g. plant sterols, fibres, lactic acid bacteria), the relevant data and rationale that the constituent reaches the target site or mediates the effect are provided. All available data on factors (e.g. forms of the constituents) that could affect the absorption or utilisation in the body of the constituent for which the health claim is made should also be provided.

3.3.4 The methodological quality of each type of study should be assessed, including study design and statistical analysis.

(a) The design of human intervention studies should notably include an appropriate control group, characterize the study groups' background diet and other relevant aspects of lifestyle, be of an adequate duration, take account of the level of consumption of the food or food constituent that can be reasonably achieved in a balanced diet, and assess the influence of the food matrix and total dietary context on the health effect.

(b) (b) Statistical analysis of the data should be conducted with methods recognized as appropriate for such studies by the scientific community and with proper interpretation of statistical significance.

3.3.5 Studies should be excluded from further review and not included in the relevant scientific data if they do not use appropriate measurements for the food or food constituent and health effect, have major design flaws, or are not applicable to the targeted population for a health claim.

3.3.6 By taking into account the totality of the available relevant scientific data and by weighing the evidence, the systematic review should demonstrate the extent to which:

(c) the claimed effect of the food or food constituent is beneficial for human health;

(d) a cause and effect relationship is established between consumption of the food or food constituent and the claimed effect in humans such as the strength, consistency, specificity, dose-response ,where appropriate, and biological plausibility of the relationship;

(e) the quantity of the food or food constituent and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet as relevant for the target population for which the claim is intended;

(f) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

3.3.7 Based on this evaluation and the substantiation criteria, competent national authorities can determine if, and under what circumstances, a claimed relationship is substantiated.

4. SPECIFIC SAFETY CONCERNS

4.1 When the claim is about a food or food constituent, the amount should not expose the consumer to health risks and the known interactions among constituents should be considered.

4.2 The expected level of consumption should not exceed relevant upper levels of intake for food constituents.

4.3 The exposure assessment should be based on an evaluation of the distribution of usual total daily intakes for the general population[2,3] and, where relevant, those for vulnerable population groups. It should account for the possibility of cumulative intake from all dietary sources, and of nutritional imbalance due to changes in dietary patterns in response to information to consumers that lays emphasis on the food or food constituent.

5. RE-EVALUATION

Health claims should be re-evaluated. Competent national authorities should re-evaluate health claims either periodically or following the emergence of significant new evidence that has the potential to alter previous conclusions about the relationship between the food or food constituent and the health effect.

[2] Food and Nutrition Board, Institute of Medicine, National Academy of Sciences. Dietary Reference Intakes: A Risk Assessment Model for Establishing Upper Intake Levels for Nutrients. Washington, D.C. National Academy Press, 1998, p. 8.
[3] European Commission, Scientific Committee on Food. Guidelines of the Scientific Committee on Food for the Development of Tolerable Upper Intake Levels for Vitamins and Minerals. SCF/CS/NUT/UPPLEV/11 Final. 28 November 2000. p.4.

REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

MALAYA AT MALUSOG NA PAMAYANAN

October 18, 1991

OFFICE ORDER
No. 22 s. 91

TO : The Product Services Division and All Personnel Concerned

SUBJECT : Guidelines for the Classification of Vitamins and Minerals as Drug or as Food

The National Drug Committee (NDC) in a letter dated August 5, 1991 has recommended to BFAD the guidelines for the classification of vitamins and minerals as food or as drug. The said recommendation is hereby adopted, and we quote:

1. Vitamins and Minerals FDC shall be **classified as drug** based on the following criteria:

   a. the clinical therapeutic indication or claim made for the preparation is for the preparation is for a specific vitamin deficiency or state or disease;
   b. the strength or concentration per dosage form is >105% RDA for fat soluble and >150% RDA for water soluble vitamins;
   c. it is in pharmaceutical dosage form/or injectable form;
   d. it is highly purified; and
   e. additional pharmacologically active ingredient(s) is (are) present.

2. Vitamins and Minerals FDC shall be **classified as food supplements** based on the following criteria:

   a. the indication for the preparation is as dietary supplement;
   b. the strength or concentration per dosage form is <105% RDA for fat soluble and <150% RDA for water soluble vitamins;
   c. it may be available as non-pharmaceutical or pharmaceutical dosage form except parenterals;
   d. it may be available as purified or as natural product; and
   e. there are no additional pharmacologically active ingredient(s)

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SUMMARY:

	CRITERIA	DRUG	FOOD
1.	Clinical Therapeutic Indication or claims made for the preparation	Specific Vitamin deficiency state or disease	Dietary Supplement
2.	Strength or concentration / dosage form	Fat Soluble: >105% RDA Water Soluble: >105% of RDA	Fat Soluble: <105% = of RDA Water Soluble: <150% = of RDA
3.	Form	Pharmaceutical dosage forms and all injections	Pharmaceutical dosage form except parenterals or non-pharmaceutical form
4.	Purity	Purified	Natural product or purified
5.	Additional Pharmacologically Active Ingredients	Present	None

Henceforth, these guidelines shall govern the registration of vitamins and minerals. Any matters or any issues not covered by this Order shall be submitted to the Office of the Director and/or BFAD Management Committee for decision.

(Original Signed)
QUINTIN L. KINTANAR, MD, PhD
Director
Assistant Secretary of Health
For Standards and Regulation

Administrative Order No. 50 s. 2001 Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs. *****

A. Fees for Licensing of Establishments regulated by BFAD (LTO) – Food Establishments only

CLASSIFICATION	FEES (PESOS)	
	Initial (1 year validity)	Renewal (2 years validity)
1. Food Distributors Importer, Exporter, Wholesaler	4,000.00	8,000.00
2. Food Manufacturer		
2.1. 1 Million and below	1,000.00	2,000.00
2.2. Over 1 Million but below 5 Million	2,000.00	4,000.00
2.3. 5 Million but below 10 Million	3,000.00	6,000.00
2.4. 10 Million but below 20 Million	5,000.00	10,000.00
2.5. 20 Million but below 50 Million	10,000.00	20,000.00
2.6. 50 Million and above	15,000.00	30,000.00
3. Others		
3.1. Amendment of LTO or Re-issuance (if lost)	500.00	
3.2. Addition or deletion of sources	50.00/source; 300 if >5 sources	
3.3. Certification/Clearance for BOC purposes and Donation	500.00	
3.4. Change of Business name/address of supplier	500.00	

Note:

1. The fees charged for manufacturers and traders of products regulated by BFAD are based on the capital invested.
2. Renewal of LTO shall be on the anniversary of its issuance and shall be valid for two years.
3. A surcharge****** of 25% of annual fee shall be charged per quarter (every three months) of delay in filing an application for renewal of the LTO.

B. Fees for Registration of Products regulated by BFAD

CLASSIFICATION	FEES (PESOS)	
	Initial (1 year validity)	Renewal (5 years validity)
1. Food		
1.1. Category 1	200.00	1,000.00
1.2. Category 2	250.00	1,250.00
1.3. Food Supplement	1,000.00	5,000.00
1.4. Bottled Water	1,000.00	5,000.00
2. Reapplication	200.00	
3. Amendment	200.00	
4. Re-issuance of CPR	500.00	
5. Extension of Shelf-life	1,000.00	

Note:

1. Initial registration for the different categories of products may be valid for 2, 3, 4 or 5 years with payment of corresponding fees, except food supplement for which maximum is 2 years.
2. Renewal of registration is for a five-year duration starting on the date of expiration of the CPR.
3. A surcharge** of 50% of renewal fee is collected if renewal fee is collected if renewal is submitted within 3 months after the expiration of the Certificate of Product Registration (CPR). Application for renewal filed beyond the third month after expiration of CPR shall be considered as initial application.
4. Local or imported food products shall be classified according to Category I and Category 2 of Bureau Order No. 163, s. 1997

** Fees may be subjected to increase upon issuance of new Administrative Order in the future.*

***Please refer to FDA Circular 2011-004 for the computation of surcharge*

DEPARTMENT OF HEALTH

FOOD AND DRUG ADMINISTRATION

Center for Food Regulation and Research

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Address Letter to:	**NELA CHARADE G. PUNO, RPh** **Director General** **Food and Drug Administration** **Attn: PILAR MARILYN M. PAGAYUNAN** **Director IV** **Center for Food Regulation and Research**