Republic of the Philippines
Department of Health
Bureau of Food and Drugs
Alabang, Muntinlupa City

22 December 1997

BUREAU ORDER
No. 163 s. 1997

SUBJECT: **SPECIFIC REQUIREMENTS FOR THE REGISTRATION OF IMPORTED FOOD AND FOOD PRODUCTS**

Department of Health Administrative Order No. 37 s. 1979 provides that imported food and food products shall be registered with BFAD prior to their distribution into commerce. However, the existing processes and requirements for registration adopted since the issuance of the said order are perceived to be no longer reasonable and consistent with the current legitimate trade practices.

In order, therefore, to update the processes and requirements for registration with the end in view of facilitating compliance with the requirements for registration and ensuring that the consumers are adequately protected from adulterated, misbranded and otherwise substandard food products, the following systems and requirements for registration are hereby prescribed.

I. Registration Systems

Two systems of registration shall be adopted by BFAD which shall apply to imported food products classified into Category I and II, listed in Annex "A" hereof.

A. Registration of Category I Products

1. Registration of imported food products under Category I shall be based on the evaluation of the following:

   a) importer's guarantee in the form of an affidavit attesting that the products contain ingredients and additives that are permitted for use in human food and in accordance with relevant regulations issued by BFAD; and

   b) compliance with the Codex recommended standard for labeling of prepackaged foods and BFAD labeling rules and regulations.

2. Products registered under this system may be subject to examination at any time during the validity of registration and the cost of laboratory analysis shall be charged to the imported. The Product Services Division, Laboratory Services Division and Regulation Division I shall determine the appropriate monitoring scheme for these products.

B. Registration of Category II Products

I. Registration of imported food products under Category II shall be based on the evaluation of the following:

   a. products' specifications which shall be validated by appropriate certificate of analysis from the country of origin or from a BFAD recognized laboratory.

b. Compliance with the Codex recommended standard for labeling of prepackaged foods and BFAD labeling rules and regulations; and

c. BFAD's own examination of the product for verification of conformity to prescribed standards for safety and quality.

II. Registration Requirements

A. Applications for registration shall be submitted to BFAD together with the documents / requirements indicated in Annexes "B" and "C".

B. For products whose labels do not indicate the name and address of the manufacturer, the importer/applicant shall declare in his application the name and address of the manufacturer. In case the source of the importer is a consolidator who has no knowledge of the name and address of the importer, the application for registration shall be provisionally granted on condition that the importer shall submit the name and address of the manufacturer within three (3) months from the date of application. Failure to do so shall automatically cancel the certificate of product registration without further notification.

C. Importers shall notify BFAD of the expected shipments at least one (1) month before the estimated date of arrival by submitting the list of food products to the BFAD Regulation Division I. The list of products to be imported shall be prepared in two copies, one of BFAD records and the other for the importer. BFAD shall acknowledge the receipt of the submitted list of products and shall notify the importer and the Bureau of Customs in case there is a need for inspection and/or sampling of the incoming shipments. Inspection and/or sampling may be conducted at the port of entry or at the importer's warehouse.

III. Validity of Certificate of Product Registration

The certificate of product registration (CPR) shall be valid for two (2) years and subsequent renewal of CPR shall be valid for a period of three (3) years.

IV. Fees

The importer/applicant shall pay for the registration fees prescribed by the DOH or BFAD as the case may be. Pending the review and revision of existing fees, application filed beginning January 2, 1998 shall be accompanied by payment of registration fees existing at the time of filing. Revised fees shall be applied prospectively or to application after such revision shall have been approved and authorized.

This Order shall be effective fifteen (15) days after its publication in the newspaper of general circulation.

(Sgd) QUINTIN L. KINTANAR, MD.Ph.D.
Director IV – CESO I

Annex "A"

PRODUCT CATEGORY

CATEGORY I	CATEGORY II
Bakery and bakery related products	Alcoholic beverages
Non-alcoholic beverages & beverage mixes	Food Supplements
Candies & confectionery products	Tea (Herbal)
Cocoa & cocoa related products	Bottled Drinking Water
Coffee, Tea and non-dairy creamer	Foods for Infant & Children
Condiments, sauces and seasonings	Foods for Special Dietary Use
Culinary products	Transgenic food products (use of generic engineering / biotechnology)
Gelatin, dessert preparation & mixes	
Dairy Products	Ethnic food products with indigenous ingredient (s) not
Dressings & Spreads common in the Philippines.	
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 shortening	
Snack foods and breakfast cereal	
Sugar and other related products	

Annex "B"

REQUIREMENTS FOR REGISTRATION OF IMPORTED FOOD PRODUCTS (CATEGORY I)

1. Letter of application for registration from Importer/Distributor

2. Accomplished Affidavit of Undertaking (1), typewritten and should be duly notarized (xerox copy not allowed)

3. Accomplished product list by product classification, 3 copies (typewritten)

4. Valid License to Operate with supplier's source(s) of imported food products.

4. Xerox copy of the sales invoice (bring original for cross checking)

6. One sample of each product in commercial presentation and a copy of label that is in conformance of Codex Labelling Regulations and BFAD requirements. (In lieu of product sample, a colored picture of each product may be submitted)

   *A Sticker indicating the name and address of the importer must be attached if not printed on the label.

7. A fee of P 25/product.

Annex "C"

CHECKLIST OF REQUIREMENTS FOR THE REGISTRATION OF IMPORTED FOOD PRODUCTS (CATEGORY II)

1. Letter of application for registration from Importer/Distributor

2. Valid License to Operate

3. Product Information

   a. List of ingredients in decreasing order of proportion. For additives with prescribed limit, the amount added must be indicated.

   b. Finished product specification (physico-chemical and microbiological)

4. Samples of the product in its commercial presentation. (See attached list of minimum product samples for laboratory analysis)

5. Loose label and labelling materials to be used for the products.

6. Estimated shelf life, parameters used and methods for determining shelf life.

7. Brief description/flow diagram of the method of manufacture.

8. Certificate of analysis. Include analytical methods used. Additional requirements for food supplement may apply as necessary.

9. Registration Application Fee + Cost of laboratory analysis (prior to release)

AFFIDAVIT OF UNDERTAKING

_____ of legal age, _____
(name of applicant) (position in the company)

and/or duly authorized representative of _____
(name of company and address)

_____, after having been sworn in accordance with law, hereby declare that:

1. the aforementioned company has imported from _____
(country of origin)
the food products: see attached product list
2. the said importation is covered by the sales invoice no. _____ of the _____, copy of which is cross-checked with the original and
(source/principal of the importer)
attached as Annex A;
3. the applicant company has a valid License to Operate as an importer, with LTO No. _____ covering the said shipment.
4. the said products are not adulterated nor misbranded, and contain ingredients and additives that are permitted for use in human food and in accordance with relevant regulations issued by BFAD.
5. as duly authorized person of the _____
(company name)
he undertaken to be responsible and accountable for the quality, safety and truth in the labelling declaration of the said food product.
6. he further undertaken to indicate his company name and address by stick-on labelling or by other means of the labelling of the products in the market.
7. He furthermore understands and agrees that the products may be subjected to BFAD laboratory examination at any time to verify the products safety, quality and conformity with labelling claims and that the cost of laboratory examination shall be charged to them.
8. He executed this affidavit to confirm the truth of the foregoing.

_____ at _____
(Date) (Place of execution)

_____
(affiant)

Subscribed and sworn to before me this _____ day of _____ with Issued on _____ at _____.

Notary Public

PRODUCT LIST

Company Name: _____
Address: _____
Product Classification: _____

Brand Name	Product Name	Description of Packaging	Country of Origin	Supplier's Name and Address	
				Manufacturer	Distributor

_____
(Print Name over Signature)

[COMPANY LETTERHEAD]

The Director
Food and Drug Administration
Civic Drive, Filinvest Corporate City,
Alabang, Muntinlupa City

Attention: **Product Services Division**

Sir/Madam:

In accordance with R.A. 9711 and other related issuances, we wish to apply for the registration of our product/s:

PRODUCT/S*	TYPE OF REGISTRATION**		
	INITIAL	RE-APPLICATION	RENEWAL

** Provide additional row/s if more than one product is applied.*
*** Check the type of registration applied.*

Along with this application are the documents listed in the checklist of requirements for registration and the representative sample of our products.

We categorically declare that all data and information submitted in connection with this application as well as other submissions in the future are true and correct.

We further agree and bid ourselves that any change in the formulation, labeling, technical specification, or any deviation on any information given in respect of this application will first have to be cleared and approved by FDA.

Date: _____

Company Name:
_____

By:
_____
Indicate Authority
(e.g. whether owner / proprietor / partner
or duly authorized representative of the Company)