



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



30 September 2014

FDA Circular
No. **2014-024**

SUBJECT: Rules and Regulations on Securing FDA Authorization for Food and Cosmetic Micro Enterprises and their Products in Collaboration with the Department of Trade and Industry (DTI) Negosyo Centers and the Local Government Units (LGUs)

I. Rationale/Background

The Department of Trade and Industry (DTI) and the local government units (LGU) have simplified business registration process for micro, small and medium enterprises (MSMEs), and have made it easier for applicants to apply for business permits issued at the municipality or city level and barangay. The simplification of the process was due to the efforts made by the DTI and the LGUs to increase productivity and improve competitiveness of MSMEs.

For micro enterprises engaged in food processing and cosmetic manufacturing, business operators are also required to secure license to operate (LTO) issued by the FDA and market authorization for each product that they manufacture and offer for sale or use.

The MSMEs play significant role in developing the Philippine economy. They provide jobs for the country's growing labor force and progress across the country. They serve as valuable partners to large enterprises as suppliers and provide support services SMEs. A vibrant MSME sector is an indication of a growing economy.

As of 2012, the DTI reported that there are 944,897 business enterprises operating in the Philippines. Of these, 99.58% (940,886) are MSMEs and the remaining 0.42% (4,011) are large enterprises. Of the total number of MSMEs, 89.78% (844,764) are Micro enterprises, 9.78% (92,027) are small enterprises, and 0.44% (4,095) are medium enterprises.

The ASEAN Economic Community Blueprint offers opportunities and challenges for micro entrepreneurs in the cosmetic and food sectors. Food and cosmetic micro enterprises have unique demands, if not needs, in terms of government support in order to be integrated into the mainstream market and to contribute to the competitiveness and flexibility of SMEs towards a single market and production base in ASEAN and the rest of the economies.



Cosmetic products, including fragrance and toilet or bath soap as well as laundry or dishwashing soap bars, pastes, detergents and liquid, and other related products, that contain chemical ingredients may be hazardous to health, and as such the manufacture and sale of these products should be regulated pursuant to RA No. 3720 (Food, Drug and Devices, and Cosmetic Act), RA No. 9711 (The FDA Act of 2009) and the ASEAN Cosmetic Directives (ACD). The ACD since 2008 was adopted by the FDA Center for Cosmetic Regulation and Research (CCRR), and required business operators LTOs and to notify the FDA, through an electronic notification scheme, before placing their products in the market.

Under the notification scheme, the FDA no longer undertakes a substantive review of cosmetic products before a product is placed in the market. In fact, the notification scheme is done online and payments may be made through the bank. The market authorization can be received in 17 days. The LTO can be processed in one month if the requirements are complete. Companies are no longer required to submit their product ingredient list, however, the onus of ensuring safety and quality rest with the companies submitting the notifications. The FDA conducts post-marketing surveillance through inspection, sampling of products in the market, and verification of the product information file.

By virtue of RA No. 9711 and RA 3720, all food business operators engaged in the manufacture of processed food in the country are required to secure FDA LTOs.

Product registration or market authorization was required in the past for the following products only: a) imported products, b) locally produced products for exports, c) locally produced products to be advertised, and d) products that are covered by special law like bottled water and food that are required to be fortified. Locally produced were not required to be registered at the BFAD, unless covered by the above. Raw materials and ingredients were not required to be registered either. However, RA 9711 changed that - *Section 10. Section 11, subsections (a), (b), (d), (g), (j), (k) and (l) of Republic Act No. 3720, as amended, are hereby further amended to read as follows: "SEC. 11. The following acts and the causing thereof are hereby prohibited: "(a) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product that is adulterated, **unregistered** or misbranded.*

Republic Act No. 10611, otherwise known as the Food Safety Act of 2014 under Section 28. Licensing, Registration of Establishments reinforced the provision of RA 9711 for food and food products – *Appropriate authorizations shall be developed and issued in the form of a **permit, license and certificate of registration** or compliance that would cover establishments, facilities engaged in production, post-harvest handling, processing, packing, holding or producing food for consumption in accordance with the mandated issuances of regulatory agencies issuing such authorizations. **Special derogations shall be provided due to geographical location and after an assessment of risks, especially for micro, small and medium-sized food business operators and health products.***

This Circular is being issued to provide guidelines on how to secure authorization from the FDA for micro food and cosmetic business operators, consistent the objectives of RA No. 10644, s. 2014, (*Go Negosyo Act*), RA No. 9501, s. 2008, (*Magna Carta for MSMEs*) and RA 9178, *Barangay Micro Business Enterprises Act* of 2002.

II. Objective

The objective for issuing this Circular is to provide guidelines in collaboration with the DTI and the LGUs on securing FDA LTOs for micro enterprises and market authorization for products produced by them, such that the process of application and approval are made simple and compatible with the DTI and LGU processes.

III. Scope and Coverage

This Circular shall apply to all micro enterprises engaged in the manufacture and distribution-wholesale of cosmetic products, including fragrance and toilet or bath soap as well as laundry and dishwashing soap bars, pastes, detergents and liquid, and other related products; and processed food products. It shall not apply to small, medium and large enterprises.

It shall not cover business operators as distributors engaged in distribution-import or export.

This Circular shall not cover the regulatory mandates and functions of other government agencies for fresh plant, animal, fisheries and aquaculture foods as well as the development and enforcement of food safety standards and regulations for foods in the primary production and post-harvest stages of the food supply chain that are observed by farmers, fisherfolk and other food business operator. It shall not also cover food businesses such as, but not limited to, activities in slaughterhouses, dressing plants, fish ports, wet markets, supermarkets, school canteens, restaurants, catering establishments, water refilling stations, street food sale, including ambulant vending under the purview of the Local Government Units.

IV. DEFINITION OF TERMS

For the purpose of implementing this Circular, the following terms are hereby defined:

1. Authorization means a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and/or, where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption, or any similar

document. A Certificate of Product Registration (CPR) and Product Notification, among other similar documents, are market authorization issued by the FDA.

2. MSMEs as any business activity or enterprise engaged in industry, agri-business and/or services, whether single proprietorship, cooperative, partnership or corporation whose total assets, inclusive of those arising from loans but exclusive of the land on which the particular business entity's office, plant and equipment are situated, and have value falling under the following categories:
 - a) micro: not more than P3,000,000;
 - b) small: P3,000,000 to P15,000,000;
 - c) medium: P15,000,001 to P100,000,000; and
 - d) large: P100,000,001 and up.
3. Establishment is an economic unit, which engages, under a single ownership or control, i.e. under a single entity; in one or predominantly one kind of economic activity at a single fixed physical location. The operational definition of establishment is the unit that is engaged in the production of the most homogeneous group of goods and services, usually at one location, but sometimes over a wider area, for which separate records are available that can provide data concerning the production of these goods and services and the materials, labor and physical resources used in the production.
4. Distributor-importer/exporter means any establishment that imports or exports raw materials, active 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.
5. Distributor-wholesaler means any establishment that procures raw materials, active ingredients and/or finished products from a local establishment for local distribution on wholesale basis.
6. 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.
7. Cosmetics means any substance or preparation intended to be placed in contact with the various external parts of the human body or with the teeth and the mucous membranes of the oral cavity, with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and for correcting body odor, and for protecting the body or keeping them in good condition.
8. Food Business Operator refers to a person engaged in the food business including one's agents and is responsible for ensuring that the food business under one's control comply with government rules and regulations.

9. 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.
10. 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.
11. Primary production refers to the production, rearing or growing of primary products including harvesting, milking and farmed animal production up to slaughter; and the rearing and growing of fish and other seafood in aquaculture ponds. It also includes fishing, and the hunting and catching of wild products.
12. 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 and a combination of those processes intended to produce food.
13. Product Information File or PIF means a file administrative and technical documents concerning the licensed establishment and products with market authorization that are kept by the owners (not necessarily submitted to the FDA) ready for inspection. It shall be updated, and all reports and current and old documents shall be kept on file.
14. Licensing by the DOH-FDA means the process of approval of an application by the DOH-FDA 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 for sponsorship of processed and prepackaged food products.
15. Prepackaged is processed food made up in advance in a container, labeled and ready for sale to the consumer, or for catering purposes.

V. National Policies on MSMEs

The following legal mandates and national policies shall serve as the guide in implementing this Circular:

1. Republic Act No. 10644, An Act Promoting Job Generation and Inclusive Growth Through the Development of Micro, Small and Medium Enterprises or the “Go *Negosyo* Act”, which states:
 - a. It is the policy of the State to foster national development, promote inclusive growth, and reduce poverty by encouraging the establishment of MSMEs that facilitate local job creation, production and trade in the country.
 - b. The State shall develop plans and initiate means to ease the constraints on the establishment of MSMEs in order to rationalize the existing bureaucratic regulations, providing greater incentives and benefits to MSMEs, and strengthening the Micro, Small and Medium Enterprise Development (MSMED) Council.
 - c. There shall be established under the supervision of the Micro, Small and Medium Enterprise Development (MSMED) Council, a “*Negosyo* Center” in all provinces, cities and municipalities.
 - d. The *Negosyo* Center of each city or municipality shall facilitate and expedite the business application process of MSMEs in coordination with the LGUs and other concerned agencies and coordinate with the respective local government units (LGUs) and liaise with concerned government agencies to process the duly accomplished forms submitted by the MSMEs.
 - e. A unified and simplified business registration form shall be developed by the DTI and shall be made available in all *Negosyo* Centers. The unified business registration form shall contain all necessary information for the business application process of MSMEs. The DTI shall be responsible for regularly updating and maintaining the unified business registration forms.
2. Republic Act No. 10611, otherwise known as the Food Safety Act of 2014, which states:
 - a. The food business operators (FBO) shall ensure that, food satisfies the requirements of food law relevant to their activities in the food supply chain and that control systems are in place to prevent, eliminate or reduce risks to consumers.
 - b. The FBO shall be knowledgeable of the specific requirements of food law relevant, to their activities in the food supply chain and the procedures adopted by relevant government agencies that implement the law. They shall adopt, apply and be well informed of codes and principles for good practices. The Micro and small industries shall be assisted to facilitate their adoption of such practices.
 - c. The DILG and the LGUs shall be responsible for the enforcement of the “Code on Sanitation of the Philippines” (Presidential Decree No. 856, December 23,

1975), food safety standards and food safety regulations where food is produced, processed, prepared and/or sold in their territorial jurisdiction.

- d. Appropriate authorizations shall be developed and issued in the form of a permit, license and certificate of registration or compliance that would cover establishments, facilities engaged in production, post-harvest handling, processing, packing, holding or producing food for consumption in accordance with the mandated issuances of regulatory agencies issuing such authorizations.
- e. Special derogations shall be provided due to geographical location and after an assessment of risks, especially for micro, small and medium-sized food business operators and health products.
- f. The skills training and other instructional/educational activities shall be regularly provided to food business operators, food handlers and to government personnel as follows:
 - i. Food business operators particularly micro, small and medium scale enterprises shall be trained on the requirements of food safety regulations and the understanding of these requirements. Personnel shall be trained on HACCP, on the codes of good practice and on technologies that will enable them to comply with regulations;
 - ii. Mandatory training on safe food handling and similar courses shall be implemented for food handlers of food businesses; and
 - iii. Government personnel shall be trained on the scientific basis for the provisions of the law and on the conduct of official controls (Section 31).

VI. Guidelines on Securing LTO for Micro Enterprises

- 1. The FDA shall issue the FDA License to Operate (LTO) in collaboration with the DTI and the LGU. After the applicant has applied for a Business Permit through the DTI *Negosyo* Center, and the LGU has issued the Business Permit, the FDA shall issue the LTO as micro food or cosmetic enterprise; Provided that
 - a. The Sanitary Permit has been issued by the LGU based on the Certificate of Compliance, which was issued by the FDA-trained and deputized Sanitary Inspector(s).
 - b. The Health Certificates have been issued to all food handlers or cosmetic workers and owners or business operators, but only after undergoing a training course recognized by the FDA. The training course shall be appropriate to the level of risk of the business operation and products produced, e.g. food safety training on processed/prepackaged food products or ASEAN Cosmetic Directive Manual and GMP.

2. A training course with specific topics to address the level of risk of products, e.g. potential contamination of pathogens or ability to support formation of toxins or growth of pathogens, shall be required for food business operators and food handlers. The food handlers and food business operators shall be required to undergo food safety training course under the supervision of the FDA MSME Affairs every two years.
3. A training course on ASEAN Cosmetic Directive Manual and basic GMP shall be required for cosmetic business operators and workers every two years. The FDA MSME Affairs shall collaborate with NGOs, private and public entities on the conduct of the training courses.
4. The LGU, in collaboration with the MSME Affairs, shall continuously train its sanitary inspectors on food safety and/or on the ACD Manual and GMP. The LGU or FDA may collaborate with other government agencies, private or public organizations or the industries in designing, planning or conducting the training courses.
5. Inspections based on consumer complaints or spot checking shall be done by the FDA Inspectors or deputized Sanitary Inspectors.
6. The following specific requirements (when applicable) shall be part of the Product Information File (PIF) to be kept by the operator and to be shown upon inspection.
 - a. Name of product(s) to be produced or being produced, distributed
 - b. Description of the products to be manufactured (e.g. source of the ingredients is important for traceability)
 - c. Description of processing/preparation procedure, showing a flowchart with quality control points as appropriate to the size of operation or to address risk if any
 - d. Description of quality control procedures, as appropriate to the size of operation or to address risk if any
 - e. Result of analysis of product(s) showing compliance with applicable standards, as appropriate to address the level of risk
 - f. Description of transits/traffic for raw materials, products and by-products, and refuse or garbage (e.g. flow of process from raw materials/ingredients to finished products)
 - g. Facsimile of product label (*for food micro enterprise, the minimum labeling requirement shall be based on RA 7394 or the Consumer Act of the Philippines; claims shall be substantiated.*)
 - h. Agreement with the source of the product(s) to be sold or offered for sale

Should there be any other requirements that may be needed to ensure food safety and veracity of product, AO No. 2014-0029 shall be used.

7. The following fee for the LTO shall be charged by the FDA per establishment per year:
 - 7.1. Micro Food Enterprise: P1,000 (*Administrative Order No. 50, s.2001; FDA Circular No. 2011-003 and FDA Circular No. 2001-003A (Subject: Collection of Legal Research Fee Imposed by RA No. 3870 as amended by PD 200 and further amended by PD 1856)*)
 - 7.2. Cosmetic Enterprise: P5,000 (*Administrative Order No. 50, s.2001; FDA Circular No. 2011-003 and FDA Circular No. 2001-003A (Subject: Collection of Legal Research Fee Imposed by RA No. 3870 as amended by PD 200 and further amended by PD 1856)*)
 - 7.3. The fees and charges for micro enterprises may be increased only upon issuance of an Administrative Order signed by the Secretary of Health.

I. Guidelines on Securing Product Market Authorization

1. An application for a product market authorization shall be filed only after the LTO has been issued by the FDA.
2. The application for product market authorization shall be filed to the FDA Regional Cluster or Regional Office through the DTI *Negosyo* Center. However, should the FDA have online application service or an application through a product notification/registration system, the applicant shall use this service or system.
3. The application requirements are as follows:
 - 3.1. Affidavit of Undertaking (*truthfulness/authenticity of documents submitted, compliance to FDA rules and regulations, among other responsibilities*) and TIN
 - 3.2. Photocopy of Business Permit issued by the LGU
 - 3.3. Proof of Payment

The following shall be made available together with Product Information File (PIF), as appropriate, and shall be presented upon inspection:

- a. Clear and complete loose label or artwork, as applicable, for all packaging sizes.
- b. For food, minimum labeling requirement based on RA 7394, Consumer Act of the Philippines;
- c. For cosmetics, ACD labeling requirements shall be followed
- d. All claims shall be substantiated; for logo/seal used on the label, the certificate or certification (e.g. Sangkap Pinoy, Halal, Organic, or Kosher) needs to be submitted
- e. When appropriate, the basis for the claimed shelf life of the product

Should there be any other requirements that may be needed to ensure food safety and veracity of product, AO No. 2014-0029 shall be used.

When the FDA online application service or application through a product notification/registration system is available, the applicant shall submit requirements as required by the service or system.

4. The market authorization shall apply on per packaging per product basis.
5. The following fee shall be charged by the FDA per product per year:
 - 5.1. Food: P250 (*Administrative Order No. 50, s.2001; FDA Circular No. 2011-003 and FDA Circular No. 2001-003A (Subject: Collection of Legal Research Fee Imposed by RA No. 3870 as amended by PD 200 and further amended by PD 1856)*)
 - 5.2. Cosmetic: P500, plus P100 per variant (*Administrative Order No. 50, s.2001; FDA Circular No. 2011-003 and FDA Circular No. 2001-003A (Subject: Collection of Legal Research Fee Imposed by RA No. 3870 as amended by PD 200 and further amended by PD 1856)*)
 - 5.3. The fees and charges may be increased only upon issuance of an Administrative Order signed by the Secretary of Health.
6. Should there be a deficiency that needs to be complied by the micro enterprise, the business operator may be assisted by the DTI *Negosyo* Center staff and DOST MSME Program staff or any private or public organization supporting MSMEs for clarity or efficiency in completing the requirements.

II. Other Conditions

1. Should there be a discrepancy in the amount of fee already paid by the micro enterprise which has a currently valid LTO or market authorization issued by the FDA, it shall continue to pay the current fee, unless a new Administrative Order is issued by the DOH Secretary of Health on fees and charges. Upon renewal of the authorization, however, the existing fees and charges shall apply.
2. Micro enterprises are prohibited from distributing or supplying to supermarkets and groceries and other small, medium or large enterprises, they have only a Business Permit issued by the LGU. Processed food products, however, may be sold directly to consumers or in retail outlets that they own or rent/lease only after securing market authorization. An FDA LTO and a CPR is required in order to distribute or supply to supermarkets and groceries and other small, medium or large enterprises. For other institutions, like hotels and restaurants, distribution is allowed provided that the micro enterprises inform their customers or patrons that they do not have a valid FDA authorization yet and that they issue an official receipt per delivery or transaction.

III. Relevant Roles of the LGU, DTI and FDA

1. FDA
 - 1.1. The FDA Field Regulatory Operations Office shall, among others:

- a. develop at the regional level its capability to inspect micro enterprises and to train or capacitate and deputize the LGU Sanitary Inspectors;
 - b. develop at the regional level its IT-based system and procedure to collaborate with the DTI-Negosyo Center in receiving, forwarding, evaluation and issuance of all license and registration applications; and
 - c. develop an inspection manual for micro and small enterprises to be cascaded to the Sanitary Inspectors.
- 1.2. The FDA MSME Affairs shall collaborate with the FDA Center for Cosmetic Regulation and Research or the Center for Food Regulation and Research or with the FDA Academy, other government agencies, such as the DTI-BMSMED, institutions, like universities and colleges, or organizations in conducting or recognizing training courses appropriate for micro enterprises.
 - 1.3. The FDA Inspectors shall conduct post-market surveillance and spot checking inspection to ensure continuous compliance of micro and small enterprises to standards and regulations of the FDA.
 - 1.4. The FDA shall deputize sanitary inspectors to conduct inspections in FDA-licensed establishments.
 - 1.5. The FDA shall monitor the performance and continue to update the knowledge, skills and other competencies of deputized LGU Sanitary Inspectors.
 - 1.6. The FDA through the PPO shall collaborate with the DTI and LGU in developing, improving or sustaining its service to micro enterprises.

2. DTI

As the lead government agency in implementing the laws, rules and regulations in support to the MSMEs, the DTI and agencies, like the BMSMED, under it shall cooperate and collaborate with the FDA in planning and implementing programs in support to the MSMEs in the country.

3. LGU

As the main beneficiary of the government program for the growth and development of MSMEs at the local government unit level, the LGUs shall develop and establish systems and procedures consistent with the laws, rules and regulations on licensing and registration of health products implemented by the DOH-FDA. Full cooperation for during the conduct of post-market surveillance and product recall, as well as closure of erring establishments, shall extended to the DOH-FDA in order to afford full protection of the health, safety, welfare or interest of their constituents, the consumers and the general public.

X. Transition Period

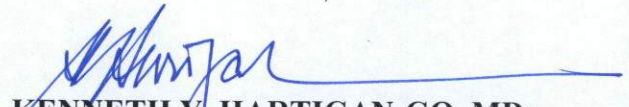
Within twelve (12) months after the signing of this Circular, the FDA Policy and Planning Office and the Field Regulatory Operations Office shall have established systems and procedures in order to fulfill the role of the FDA in collaboration with other government agencies, particularly the DTI-Bureau of Micro, Small, Medium Enterprises Development (BMSMED) and the LGUs.

XI. Separability Clause

If any part or term of provision of this Circular 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.

XIV. Effectivity

This Order shall take effect immediately upon signing.


KENNETH Y. HARTIGAN-GO, MD
Acting Director General