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

ANNEX A

PROCESSED FOOD PRODUCTS CLASSIFICATION ACCORDING TO MICROBIOLOGICAL RISK

The following list, but not limited to, shows food products identified by FDA based from the Codex Alimentarius General Standard for Food Additives (GSFA) and the UN Food and Agriculture Organization (FAO) Risk Categories:

A. LOW RISK FOODS

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.

Table 1.List of Low Risk Food Products

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 seed in 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

LOW RISK FOOD PRODUCTS (continued)

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
   c. Soybean curd (tofu)
   d. Semi-dehydrated soybean curd
      i. Thick gravy-stewed semi-dehydrated soybean curd
      ii. Deep fried semi-dehydrated soybean curd
      iii. Semi-dehydrated soybean curd, other than in LR Letter D.7.d.i) and 7.d.ii)
   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 LR Letter G.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 sauces
9. Protein products other than from soybeans, marinades

LOW RISK FOOD PRODUCTS (continued)
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

B. MEDIUM RISK FOODS

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.

Table 2. List of Medium Risk Food Products

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

MEDIUM RISK FOOD PRODUCTS (continued)
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)

C. HIGH RISK FOOD

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.

Table 3. List of High Risk Food Products

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)

HIGH RISK FOOD PRODUCTS (continued)
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

*As listed in the latest Codex General Standard for Food Additives (GSFA) 2012

ANNEX B

Hierarch of Activities

Table 4. Hierarchy of Activities – 'Y' is indicated for default activities covered by the license, 'a' is indicated for activities that may be added after licensing as an amendment, 'N' is indicated for activities not allowed.

	License to Operate as Manufacturer				License to Operate as Distributor		
Activity	**Manufacturer**	**Packer**	**Repacker**	**Trader**	**Importer**	**Wholesaler**	**Exporter**
Manufacturing	Y	a	a	N	N	Y	Y
Primary Packaging	Y	Y	N	N	N	N	N
Repackaging	a	a	Y	N	N	N	N
Import for processing	Y	a	N	a	Y	A	a
Import for distribution	N	N	N	a	Y	A	a
Wholesale	N	N	N	a	a	Y	a
Export	a	a	a	a	a	A	Y
Distribution	Y	Y	Y	Y	Y	Y	Y

ANNEX C

Requirements for Application of License to Operate

A. **Requirements for Initial Licensing** – The following are the requirements for application by an establishment:

1. Accomplished Integrated Application Form as prescribed by current FDA regulations;
2. Proof of Payment of Fees as prescribed by current FDA regulations;
3. Proof of Business Registration
   a. If Single Proprietorship: Valid Certificate of Business Name Registration with the Department of Trade and Industry indicating the same name, address and ownership as the establishment applying for a license;

   b. If a Corporation or Partnership:
      i. Valid Registration with Securities and Exchange Commission (SEC) indicating the same name, address, and ownership as the establishment applying for a license;
      ii. Articles of Incorporation; and
      iii. Other pertinent documents, as applicable;

   c. If a Cooperative: Certificate of Cooperative Development Authority (CDA) indicating the same name, address, and ownership as the establishment applying for a license;

4. If the business name and/or and address is different from the registered name and/or address in the DTI-, SEC-, or CDA-issued certificate, the following shall be submitted in addition to the documents specified above as applicable:
   a. If a Corporation or Partnership, SEC Certificate must reflect "Doing business under the name and style of (Name of Establishment)

   b. Valid Mayor's Business Permit or Barangay Business Permit indicating the same name, address and ownership as the establishment applying for a license;

5. Proof of Occupancy (per facility and/or address declared as part of the establishment);
   a. If the facility and/or address declared as part of application is **not owned** by the applicant:
      i. Notarized valid Contract of Lease of the space or building occupied; and
      ii. If the applicant is engaged in distribution (i.e. third-party logistics):
      -Duly notarized warehousing agreement;
   b. If the facility and/or address declared as part of application is **owned** by the applicant:
      - Copy of Transfer Certificate of Title;

6. Product List –
   a. The list of food products to be manufactured, processed with proposed brand name per product

   b. The list of products to be distributed, sold, or offered for sale or use, as appropriate, including the following information per product:
      i. Business name and address of direct source;
      ii. Business name and address of facility where the product is last packaged, if different from source;
      iii. Business name and address of facility where product is last processed, if different from last packaging site and direct source;
      iv. If product is to be imported, a unique global product identification number;

7. Location Map – a graphic illustration indicating the address, landmarks, immediate environment, type of building, and Global Positioning System (GPS) coordinates (if available) for each facility and/ or address declared part of the establishment;

8. Floor plan/ layout with dimensions

9. Specific requirements – The following are the requirements for application in addition to the General Requirements (Nos. 1-8 above) as applicable:
   a. Manufacturer/Processor
      i. Description of the products to be manufactured (e.g. list of ingredients, physico-chemical, and/or microbiological specifications)
      ii. Description of manufacturing process or food processing/preparation, including a flowchart with quality control points, as appropriate to the size of operation
      iii. Quality control procedures, as appropriate to the size of operation
      iv. Results of analysis of Finished Product /s showing compliance with applicable standards
      v. Facsimile of proposed product label, compliant with FDA standards

   b. Repacker
      i. Description of the product to be repacked (e.g. name of product, physico-chemical, and/or microbiological specifications)
      ii. Description of repacking process, including a flowchart with quality control points
      iii. Quality control procedures
      iv. Photocopy of duly notarized valid contract or agreement with the manufacturer, and, as appropriate, the License to Operate (LTO) of the manufacturer where the product will be sourced for repacking
      v. Facsimile of proposed label, compliant with FDA labeling requirements

c. Importer-Distributor of Raw Materials/Finished Products/ Ingredients/ Additives for Distribution and/or Retail

i. Each item declared in the list of food product(s) to be imported must be identified in any of the following:
   - Pro forma invoice,
   - Foreign agency agreement,
   - Appointment letter, or
   - Distributorship agreement

ii. All establishments from which the applicant sources its imports must be supported by at least one of the following documents issued by the health or regulatory authority of the country of origin or of source::
   - Valid manufacturer's certificate of registration with GMP compliance, or its equivalent,
   - Valid Sanitary Phyto-sanitary Certificate or Health Certificate,
   - Valid ISO 22000 Certification,
   - Valid HACCP Certificate, or
   - Certificate of Free Sale

iii. All certification issued by a private organization should be attested by a recognized business association or chamber of commerce.

iv. Appropriate test result or certificate of analysis routinely conducted in the country of origin or source that would indicate or show safety of the product. For test or analysis conducted in the Philippines, the applicant shall be guided by appropriate FDA standards as published in the FDA Website in addition to the recognition or accreditation of laboratories.

d. Distributor-Exporter

i. Any of the following documents issued to the applicant by the establishment from which it sources the products it exports:

   - Valid notarized distributorship agreement; or
   - Letter of appointment between FDA-licensed manufacturer and exporter

ii. Copy of valid CPR if already registered by the FDA-licensed manufacturer

e. Distributor-Wholesaler

i. Any of the following documents issued to the applicant by the establishment from which it sources the products it sells:
   - Valid notarized distributorship agreement; or
   - Letter of appointment between the applicant and FDA-licensed source

ii. Valid Certificate(s) of Product Registration if already registered by the FDA-licensed source

f. Food Trader

- Valid and notarized toll manufacturing and/or repacking agreement with FDA-licensed toll manufacturer and/or repacker.

B. Requirements for Renewal of a License

1. Regular renewal
   a. Accomplished Integrated Application Form as prescribed by current FDA regulations;
   b. Proof of Payment of Fees as prescribed by current FDA regulations; and
   c. Requirements in support of amendments, if applicable, included in the renewal application, including Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);

2. Automatic renewal – where there is no need for inspection or re-submission of requirements as required for initial applications, automatic renewal may be granted only if the following conditions are met:

   a. Submission of an affidavit of undertaking for automatic renewal with a sworn statement indicating no change or variation or, as applicable, no violation of FDA rules and regulations or non-compliance to the requirements of GMP have been committed
   b. The application for renewal was filed before the expiration date of the license; and
   c. The prescribed renewal fee was paid upon filing of the application.

C. Requirements for Amendment of a License

1. The following changes are equivalent to an initial licensing application and must satisfy all applicable requirements as specified in Section V Part A and Section V Part B or Part C, of main text of this Issuance, and surrender the previously issued license:
   a. Change of Ownership
   b. Change of Location of Manufacturing Site or Distribution Office

2. The following amendments must satisfy applicable requirements and upon approval, LTO will be re-issued:
   a. Change of Business Name
      i. Accomplished Integrated Application Form as prescribed by current FDA regulations;

ii. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);
iii. New Business Name registration from DTI/SEC. If registered address with DTI/ SEC is different from the address of the establishment, a photocopy of Business/ Mayor's Permit; and
iv. Proof of Payment of Fees as prescribed by current FDA regulations

b. Additional Product Line(s), for manufacturers
   i. Accomplished Integrated Application Form as prescribed by current FDA regulations;
   ii. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);
   iii. Compliance to GMP verified during inspection; and
   iv. Proof of Payment of Fees as prescribed by current FDA regulations

c. Additional activity(ies):
   i. Accomplished Integrated Application Form as prescribed by current FDA regulations;
   ii. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);
   iii. Compliance to GMP verified during inspection; if for additional activity as Toll Manufacturer for a Licensed Food Manufacturer; and
   iv. Proof of Payment of Fees as prescribed by current FDA regulations

d. Addition of Sources:
   i. Accomplished Integrated Application as prescribed by current FDA regulations;
   ii. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);
   iii. Scanned List of new sources, its address, name and address of the manufacturer (in cases when source is not directly the manufacturer), distributorship agreement or contract agreement, as applicable;
   iv. Scanned copy of <u>any</u> of the following original documents issued to the source by the Phil FDA (local) or the regulatory or health authority from the country of origin (for imported) per source:
      - Valid manufacturer's certificate of registration with GMP compliance, or its equivalent,
      - Valid Phytosanitary Certificate/ Health Certificate,
      - Valid ISO 22000 Certification,
      - Valid HACCP Certificate, or
      - Certificate of Free Sale; and
   v. Proof of Payment of Fees as prescribed by current FDA regulations

3. The following amendments must be made known to the FDA through notification:
   a. Deletion of activity(ies);
   b. Deletion of Source(s);
   c. Deletion of Warehouse Address; and
   d. Deletion of Manufacturing Plant Address

4. Requirements for notification of amendments are as follows:
   a. Accomplished Integrated Application Form and Notarized Declaration page in the FDA website as prescribed by current FDA regulations;
   b. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made); and
   c. Proof of Payment of Fees as prescribed by current FDA regulations

5. The following amendments must be made known to FDA through notification, submission of applicable Proof of Occupancy, and payment of appropriate fees:
   a. Addition of Warehouse Address not involving transfer of location
   b. Any change requiring modification of the submitted Proof of Occupancy

6. All other changes not identified previously, including but not limited to, the following:
   a. Change in Distribution Agreement not previously covered;
   b. Change of Manufacturing Process; and
   c. Change of Quality Control Procedure

   Must be reflected in the appropriate document that was required during initial application and shall be submitted during renewal;

7. Amendments requiring notification must be made known to the FDA within 30 calendar days of effect.
8. Amendments requiring satisfaction of initial licensing requirements must to do so within 60 calendar days of effect.
9. Amendments taking effect within 90 days prior to expiration of a current license must be declared along with the renewal, and must pay the corresponding fees as prescribed by current FDA regulations.

D. Re-issuance of a License – for additional original copies

1. Accomplished Integrated Application Form as prescribed by current FDA regulations; and
2. Proof of Payment of Fees as prescribed by current FDA regulations.

ANNEX D

Requirements for Application of Certificate of Product Registration

A. **Requirements for Initial Registration** – The following are the requirements for a product registration:
   1. Accomplished Integrated Application Form as prescribed by current FDA regulations;
   2. Proof of Payment of Fees as prescribed by current FDA regulations;
   3. Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations except for bulk raw materials, ingredients and food additives intended for further processing or for distribution to establishments/ manufacturers for further processing;
   4. 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;
   5. For food supplement, a sample in actual commercial presentation shall be submitted.
   6. 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.

B. Requirements for Renewal Registration
   1. Accomplished Integrated Application Form as prescribed by current FDA regulations;
   2. Proof of Payment of Fees as prescribed by current FDA regulations;
   3. Requirements in support of amendments included in the renewal application (not applicable for automatic renewal); and
   4. Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations except for bulk raw materials, ingredients and food additives intended for further processing or for distribution to establishments/ manufacturers for further processing.

C. Automatic Renewal of CPR
   1. Renewal of the CPR may be automatic provided that the following conditions are met:
      a. The application shall be filed before the expiration date of the CPR;
      b. The prescribed automatic renewal fee must be paid prior to filing of the application; and
      c. If there is no condition stated at the back of the issued Certificate of Product Registration. However, in case there is a condition, a scanned copy of the acknowledgment letter from FDA indicating the condition stated in the CPR had been complied, should be submitted.

2. Any application filed as automatic renewal registration shall be submitted with the FDA within 90 days before the date of its expiration.
3. Request for amendment shall not be allowed to be filed simultaneously with an application for automatic renewal.
4. Below shall be the specific cases wherein the Automatic Renewal will not apply:
   a. If the application for registration is filed after the expiry date of the CPR but within 120 days, the application shall not be qualified for automatic renewal and is subject to corresponding surcharges (this will be considered under Regular Renewal with the same FR number).
   b. If the application is filed after 120 days from the expiry date of the CPR, the application shall undergo the initial filing and evaluation procedure. It will be issued a new CPR.
   c. If there are any changes in product formulation (reformulation), this is treated as an application for initial registration.
   d. No application for renewal shall be accepted unless the prescribed renewal fee is paid.
   e. If within the 5 year validity, a violation on the product and label was monitored, there will be corresponding sanctions as indicated in Section XI of RA 9711 and CPR will be revoked/ cancelled if not complied within the period of 6 months. Food establishment will file for an initial application.

C. Amendments to the Product Registration

1. The following changes are equivalent to an initial registration application:
   a. Change in manufacturer or repacker shall be treated as initial registration; and
   b. Change of product formulation.
2. Notification of Amendments
   a. Condition
      There must be no changes in product that is an indication for initial product registration
   b. The following amendments must be made known to FDA through notification:
      i. Change/ Additional Packaging Size
      ii. Extension/ Change in Shelf-life
      iii. Change in Packaging Design/ Additional Packaging Design
      iv. Exportation of previously registered product initially for local distribution
3. Requirements for notification of amendments in Section G.2 above, are as follows:
   a. Accomplished Integrated Application Form as prescribed by current FDA regulations;

b. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);
c. Proof of Payment of Fees as prescribed by current FDA regulations;
d. Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA regulations or reflecting compliance to labeling requirements of importing country, in the case mentioned in Section G.2.2.4 (e.g. label reflecting the language of importing country); and/or
e. Stability study results with conclusion to support extension or change in shelf-life.

4. Transfer of Ownership of a Registered Product, or of a pending application:
   a. Conditions
      i. There must be no changes in the product that is an indication for initial product registration; and
      ii. The new owner must have a valid License to Operate from the FDA
   b. Requirements
      i. 4.2.1 Accomplished Integrated Application Form as prescribed by current FDA regulations;
      ii. 4.2.2 Scanned Application Letter stating clearly the intended changes (indicate changes/ amendments to be made);
      iii. 4.2.3 Proof of Agreement between previous and current owners of the product transferring ownership;
      iv. 4.2.4 Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalent as defined by FDA regulations; and
      v. 4.2.5 Proof of Payment of Fees as prescribed by current FDA regulations

5. Additional Packaging Type or Change in Packaging Material:
   a. Conditions
      i. There must be no changes in the product that is an indication for initial product registration
      ii. This is independent of the change in product description/ design.
   b. Requirements
      i. Accomplished Integrated Application Form as prescribed by current FDA regulations;
      ii. Complete labeling materials of the previously approved label and the proposed new/ additional presentation of packaging for comparison. (All information on the label including the design should be the same);
      iii. Proof of suitability of packaging material for food, including stability of the product in the new packaging;
      iv. Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalent as defined by FDA regulations; and

v. Proof of Payment of Fees as prescribed by current FDA regulations

6. Change in Product Description/ Name:
   a. Conditions
      i. There must be no changes in the product that is an indication for initial product registration
      ii. This is independent of the change in packaging material or packaging type

   b. Requirements
      i. Accomplished Integrated Application Form as prescribed by current FDA regulations;
      ii. Scanned Application Letter stating the intended changes, including justification for the change (indicate changes/ amendments to be made and the name should describe the true identity of the product);
      iii. Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalent as defined by FDA regulations; and
      iv. Proof of Payment of Fees as prescribed by current FDA regulations

7. Change in Brand Name
   a. Accomplished Integrated Application Form as prescribed by current FDA regulations;
   b. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);
   c. New product label, reflecting the change
   d. Authority from the source or the owner of the brand (if imported)
   e. IPO registration, if available
   f. Proof of Payment of Fees as prescribed by current FDA regulations

8. Change in Business Name
   a. Accomplished Integrated Application Form as prescribed by current FDA regulations;
   b. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);
   c. Proof of change in business name, e.g. License, Certificate
   d. New labeling materials, reflecting the change; and
   e. Proof of Payment of Fees as prescribed by current FDA regulations

9. Change in Importer/ Distributor
   a. Accomplished Integrated Application Form as prescribed by current FDA regulations;
   b. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);
   c. Termination of agreement/ Deed of assignment;

d. Agreement of new manufacturer/ importer/ distributor or Appointment letter
e. New labeling materials, reflecting the change/s
f. Proof of Payment of Fees as prescribed by current FDA regulations

10. Amendments requiring notification must be made known to the FDA within 30 calendar days of effect.
11. Amendments requiring satisfaction of initial licensing requirements must do so within 60 calendar days of effect.
12. Amendments taking effect within 90 days prior to expiration of a current license must be declared along with the renewal

D. Re-issuance of a Registration – for additional original copies:

1. Accomplished Integrated Application Form as prescribed by current FDA regulations; and
2. Proof of Payment of Fees as prescribed by current FDA regulations