IMPORTING FOOD PRODUCTS INTO THE UNITED STATES: U.S. RULES, REGULATIONS AND PROCEDURES

GENERAL REQUIREMENTS OF U.S. LAW - Under provisions of the U.S. law contained in the U.S. Federal Food, Drug and Cosmetic Act (FD&C Act), importers of food products intended for introduction into U.S. commerce are responsible for ensuring that the products are safe, sanitary, and labeled according to U.S. requirements. The Food and Drug Administration (FDA) is not authorized under the law to approve, certify, license or otherwise sanction individual food importers, products, labels or shipments. Importers can import foods into the United States without prior sanction by FDA, as long as the facilities that produce, store or otherwise handle the products are registered with FDA, and, prior notice of incoming shipments is provided to FDA. Imported food products are subject to FDA inspection when offered for import at U.S. ports of entry. FDA may detain shipments of products offered for import if the shipments are found not to be in compliance with U.S. requirements.

FACILITY REGISTRATION - The U.S. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 require that food facilities (other than private homes and individual farms) producing, storing or otherwise handling food products intended for sale in U.S. interstate commerce be registered with FDA. Registration of facilities can be performed on the internet, and is free of charge. For information and instructions on how to register a facility, please see FDA's web page on the subject at the following link: http://www.cfsan.fda.gov/~furls/ovffreg.html. Please note that a U.S. agent residing in the United States must be listed for each foreign facility being registered.

PRIOR NOTICE OF INCOMING SHIPMENTS: The Bioterrorism Preparedness Act of 2002 also requires importers to provide prior notice to FDA for each import shipment of food products. Prior notice of shipments must be performed over the FDA website. Information about the prior notice requirements and instructions on providing prior notice is available at the following FDA link: http://www.cfsan.fda.gov/~pn/pnoview.html.

Help with the registration and prior notice processes is available from the FDA Registration and Prior Notice Help Desk at 866-521-2297; email FURLS@fda.gov.

SAFETY AND SANITATION - The FD&C Act requires that foods imported into and sold in U.S. commerce not bear or contain any poisonous or deleterious substances which may render them injurious to health, nor consist in whole or in part of any filth, putrid, or decomposed substances, or otherwise be unfit for food. (Examples include evidence of rodent or insect infestation, or the presence of pesticides prohibited in foods or amounts of allowable pesticides in excess of established tolerances.) Foods must not be prepared, packed, or held under unsanitary condition whereby the products become contaminated with filth, or rendered injurious to health.

Manufacturers are not required to provide any sort of test results to the FDA as a condition of producing, marketing or distributing food products, nor does FDA accepts samples of food products offered for testing by manufacturers, importers or distributors. Under the requirements of U.S. food law, manufacturers and distributors are expected to take necessary and reasonable steps to ensure the safety and sanitation of their food products.

GOOD MANUFACTURING PRACTICES: Processors of food products sold in U.S. commerce should be familiar with and employ the U.S. Current Good Manufacturing Practices for foods (GMPs). The GMPs set forth basic considerations manufacturers and distributors should take into account to keep food clean and safe during manufacturing, processing, packing and holding. The GMPs are contained in Part 110 of Title 21 of the U.S. Code of Federal Regulations. They can be accessed at the following web link to Title 21 provisions: http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200321.

ACTION LEVELS: Importers of certain commodities should be aware that FDA has issued "Defect Action Levels" (DALs) for some food commodities for natural and unavoidable defects, such as mold, insect filth and mammalian excreta. These DALs specify the maximum allowable amounts of these defects in shipments of these products. FDA's DAL list can be accessed at this link to the FDA website: http://www.cfsan.fda.gov/~dms/dalbook.html.

FDA also has established action levels for poisonous and deleterious substances in certain foods. Like the DALs for natural and unavoidable defects, these action levels establish for the listed commodities the maximum allowable amounts of the listed substances. The FDA Action Levels for Poisonous and Deleterious Substances can be accessed at this link to the FDA website: http://www.cfsan.fda.gov/~lrd/fdaact.html.

RETAIL LABELING - Provisions of the FD&C Act, the U.S. Fair Labeling and Packaging Act, and the Nutrition Labeling and Education Act require that retail packages and containers of food products sold in U.S. interstate commerce bear labels in English (Spanish acceptable in Puerto Rico) that include specific information: the identity of the product, the name and address or phone number of the responsible firm (may be the manufacturer or distributor, foreign or domestic), a list of ingredients in descending order or predominance in the product, the net weight of contents in both English and metric terms, and in most cases nutritional information. This information is required to be presented in that ensures that the information is accessible to consumers under normal conditions of purchase and use. Smaller manufacturers may qualify for exemption from the requirement for nutrition labeling. Imported products are required include a label statement indicating the country of origin of the product.

Detailed information about U.S. labeling requirements can be obtained from FDA's web page on the subject at the web address http://www.cfsan.fda.gov/~dms/lab-ind.html. The first link on the main subject index of this page connects to the U.S. regulations on food labeling. The second link is FDA's "Food Labeling Guide," which was prepared to assist manufacturers in preparing labels that meet the

regulatory requirements. Further links connect to the Food Labeling Guide's appendices, which cover allowable health claims on food labels and reference sizes for nutrition labeling. Also on this webpage is a link to information about the small business exemption from nutrition labeling, including qualifications for the exemptions, and instructions on how to apply for it.

NUTRITION LABELING: For developing nutrition labeling information, manufacturers may choose to employ the services of a commercial laboratory equipped to perform analyses of foods to determine nutrient content. Manufactures can also examine the U.S. Department of Agriculture's food nutrient database to determine if the database provides information from which they can derive the appropriate nutrient information for their products. The database can be accessed at this link: http://www.nal.usda.gov/fnic/cgi-bin/nut_search.pl. FDA has developed its own Nutrition Labeling Manual, which provides technical instructions to manufacturers about how to develop and use nutrition databases for food products: http://www.cfsan.fda.gov/~dms/nutrguid.html.

LABELING BULK CONTAINERS - Bulk containers of food products offered for import into the United States should include the following information in English on the outside of the container: the identity of the product, the name and address or phone number of a responsible firm (can be the distributor, manufacturer, importer, import agent, or consignee), the net weight of contents in English measurement (pounds/ounces), a list of ingredients contained in the product, and the country of origin of the product.

ALLERGENS IN FOOD PRODUCTS, AND ALLERGEN LABELING - Food manufacturers should be aware that FDA has issued guidance about food allergens and allergen labeling of products. Agency guidance and compliance policy on the matter is available at these links to the FDA website: http://www.fda.gov/ora/inspect_ref/igs/Allergy_Inspection_Guide.htm and http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg555-250.htm.

In addition, in 2004 the U.S. Congress passed the Food Allergen Labeling and Protection Act, which will require more explicit listing of allergenic ingredients on the labels of retail food products. The law does not go into effect until January 1, 2006. Until then, all current labeling requirements remain in effect. FDA advises manufacturers to check the FDA website during this year to keep apprised of the new requirements and their implementation: http://www.cfsan.fda.gov/~dms/wh-alrgy.html.

STANDARDS OF IDENTITY - Under authority of the FD&C Act, FDA has promulgated "standards of identity" for a number of food product categories. These standards establish minimum ingredient requirements for the various foods covered by the standards. These requirements must be met in order for a food legally to be sold bearing the statement of identity covered by the standard. The standards for foods are contained in Parts 130 – 169 of Title 21 of the U.S. Code of Federal Regulations: http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200321.

LOW ACID CANNED AND ACIDIFIED FOODS - Depending on what they contain and how they are processed and packaged, certain canned or bottled

foods are "low acid canned foods" (LACF) or "acidified foods" (AF). An LACF product is a thermally processed product packed in a hermetically sealed container with an acid content above pH 4.6, containing enough water (“water activity") to allow the growth of anaerobic micro-organisms. To ensure the safety of food in U.S. commerce, LACF products are regulated more rigorously than most other foods in order to protect the products from contamination during processing by dangerous micro-organisms and their toxins, such as C. botulinum. Processors may "acidify" their low-acid canned food products by adding acidic ingredients in order to adjust the pH and inhibit microbial growth. Such products are called "acidified foods (AF)." Foreign facilities whose LACF/AF products are imported into the United States are required to register their establishments with FDA's LACF office, and, to file processing information for each LACF/AF product intended for import into the United States.

A quick reference of approximate pH values for various types of food products is available at this FDA link: http://www.cfsan.fda.gov/~comm/lacf-phs.html. For more information on LACF and AF products and their requirements, including information on how to register facilities and file processing information, see FDA's web page on this subject at the link http://www.cfsan.fda.gov/~comm/lacf-toc.html. For FDA's help with the registration process, and with determining whether your products are or are not LACF/AF products requiring facility registration and process filing, you may contact the agency's LACF office directly at the email address lacf@cfsan.fda.gov; telephone 301-436-2411. The U.S. regulations imposing the requirements for LACF/AF foods are contained in Parts 113 and 114 of Title 21 of the U.S. Code of Federal Regulations: http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200321.

FOOD ADDITIVES - FDA also regulates additives used in food products. New food additives must be approved or reviewed by FDA before marketing. FDA also regulates food packaging materials and food-contact substances. Packaging materials must be safe for use, and must not impart deleterious substances or off-flavors or odors into the packaged product. Information about FDA’s regulation of food ingredients, additives, packaging materials and food-contact substances is available at FDA’s website on the matter: http://www.cfsan.fda.gov/~lrd/foodadd.html. FDA’s list of approved food additives is contained in it’s list of Everything Added to Food in the United States (EAFUS). The EAFUS link is on the above webpage in the left-hand column near the bottom of the page.
The specific regulations in Title 21 of the U.S. Code associated with each substance in the EAFUS list are listed in the far right column of the list. (A link to Title 21 provisions is included above in this document.)

FOOD SECURITY – Food manufacturers, processors, and transporters should be aware that FDA has issued food-security guidance designed to protect their operations against the potential for bioterrorism. FDA’s guidance can be accessed at this link to the FDA website: http://www.cfsan.fda.gov/~dms/secguid6.html.

BOTTLED WATER PRODUCTS – In addition to the other applicable requirements listed here, special requirements apply to bottled water

products. FDA has promulgated a separate set of GMPs specifically for water bottling plants. These are contained in Part 129 of Title 21. In addition, FDA has promulgated regulations that stipulate definitions for various terms that may appear on the retail labels of bottled water products. These are contained in Part 165 of Title 21. You can access Part 165 provisions through the following link to Title 21 provisions: http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200321.

HACCP REQUIREMENT FOR JUICE PRODUCTS – In addition to the other applicable requirements listed here, most juice products are required to be processed in a facility that has in place a Hazard Analysis and Critical Control Point (HACCP) safety plan. Importers of juice products are required to take "affirmative steps" to ensure that facilities producing products intended for the U.S. market have an operational HACCP plan. See the following FDA link for more specific information on affirmative steps for importers: http://www.cfsan.fda.gov/~comm/juicimp.html. Information about the HACCP requirement for juice products is available at this link to the FDA website: http://www.cfsan.fda.gov/~comm/haccpjui.html.

HACCP REQUIREMENT FOR SEAFOOD PRODUCTS – In addition to the other applicable requirements listed here, seafood products are required to have been processed in a facility that has in place an operational Hazard Analysis and Critical control Point (HACCP) safety plan. Importers are required to take "affirmative steps" to assure that facilities producing products intended for the U.S. market have an operational HACCP plan: http://www.cfsan.fda.gov/~frf/sfimport.html. Information about the HACCP requirement for seafood products is available at this link to the FDA website: http://www.cfsan.fda.gov/~comm/haccpsea.html.

GOOD AGRICULTURAL PRACTICES FOR FRESH FRUITS AND VEGETABLES - FDA recommends that fruit and vegetable growers producing products intended for introduction into U.S. commerce follow certain practices to avoid contamination of the products with disease-causing organisms. FDA's full recommendations are contained in its Guide to Minimize Microbial Hazards on Fresh Fruits and Vegetables, viewable at the following link: http://www.cfsan.fda.gov/~dms/prodglan.html. The full text if the Guide can be accessed by a clickable link at the bottom of the web page. FDA urges importers to ask suppliers what steps they take to ensure that their products are safe and sanitary.

PESTICIDES: Tolerances for pesticides allowed on specific agricultural products are set by the U.S. Environmental Protection Agency (EPA). An FDA inspection of an imported agricultural commodity may test for the presence of pesticides for which EPA has not established tolerances for that commodity. Import shipments of a food commodity containing pesticides for which tolerances have not been established for that commodity may be refused entry or detained. EPA can be contacted through that agency's website at this link: http://www.epa.gov/. Specific information about what pesticides are allowed, and what amounts, in various foods is available at the following EPA link: http://www.epa.gov/pesticides/food/viewtols.htm.

PHYTOSANITARY AND ANIMAL PEST CONSIDERATIONS: Certain food products from some countries are prohibited import into the United States, or are allowed import under restricted conditions, because of the threat

of animal or plant pests and diseases. These phytosanitary restrictions are administered by the US Department of Agriculture's Animal and Plant Health Inspection Service: http://www.aphis.usda.gov/.

MEAT AND POULTRY PRODUCTS – Most meat and poultry, and combination products such as frozen casseroles and pizzas containing 3 percent or more meat by weight, are regulated by the U.S. Department of Agriculture's Food Safety and Inspection Service: http://www.fsis.usda.gov/. FSIS can be reached by email at FSIS.Regulations@usda.gov.

IMPORTING FOOD PRODUCT SAMPLES: All of the above requirements applicable to foods imported for sale in the United States also apply to imported samples of food products, except that product samples do not have to include nutrition information on the labels. However product sample labels must include the other required label information: statement of identity, net weight of contents, listing of a responsible firm, and ingredients list. FDA recommends that food product samples be labeled "not for sale" on both individual and bulk packaging.

ARRIVAL AT PORT OF ENTRY: When a food shipment is offered for import into the United States, the shipment must be declared by the importer or broker/agent to the U.S. Customs and Border Protection office at the port of entry by the filing of an "entry notice" and acquisition of a bond. Customs then will notify FDA staff of the presence of the shipment. FDA may inspect and sample the shipment to ensure its compliance with U.S. requirements. More detailed information on FDA import procedures can be found on the agency's web page on Imports and Exports at the web link http://www.cfsan.fda.gov/~lrd/imports.html. The second item on this page, "FDA Import Procedures," contains a detailed flow-chart of the process. Additional information on the FDA Import and Import Inspection system is available from the link http://www.fda.gov/ora/import/default.html.

Importers will need to know the FDA product codes for products in order to complete the on-line Import Prior Notice procedure. To determine the appropriate product code for a particular product, consult the FDA webpage on developing product codes at http://www.accessdata.fda.gov/SCRIPTS/ORA/PCB/PCB.HTM.

Information on U.S. Customs forms, procedures, bond acquisition, duties, if any, and country-of-origin labeling requirements may be obtained from any Customs Service office or from that agency's web site at http://www.customs.treas.gov/.

FDA FIELD OFFICES AND INSPECTIONS - Inspections of FDA-regulated food shipments offered for import into the United States are carried out by inspectors with the agency's Office of Regulatory Affairs. ORA offices are located throughout the United States at ports of entry. Local FDA/ORA office can also be a point of contact for importers with ports of entry within the region covered by a particular FDA/ORA office. Local, regional and district FDA/ORA are listed at this FDA link: http://www.fda.gov/ora/inspect_ref/iom/iomoradir.html.

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