Discussion Draft
Food and Drug Administration Globalization Act
Section-by-Section Analysis

Title I – Food Safety

Subtitle A—Prevention

Section 101. Changes in registration of food facilities.

Section 101 amends section 301 of the Federal Food, Drug, and Cosmetic Act to make failure to register or to pay the required registration fee a prohibited act. Amends section 415 to require annual registration and fee payment. Provides for removal from the list of registered facilities if a facility fails to reregister. Designates fees to be used for food safety activities.

Section 102. Food safety plan; process controls; performance standards.

Adds a new section 418 requiring each facility to develop and implement a written food safety plan. The Secretary of Health and Human Services (HHS) may require that a food safety plan for a facility include specific hazard controls, if such controls are needed to ensure the protection of the public health including preventing intentional adulteration of food. To protect the public health, the Secretary may establish by regulation and enforce performance standards that define the level of food safety performance that a facility shall meet.

Section 103. ***Safety standards for fresh produce.***

Adds a new section 419 in which a food safety plan shall apply with respect to the production of a type of fresh produce for consumption in the United States 1 year after the date on which the Secretary by regulation describes how a producer of such type of fresh produce may comply. The Secretary shall allow variance for local growing conditions.

Section 104. Periodic inspections of food facilities.

Adds a new section 704A providing that the Secretary shall provide for unannounced inspections of facilities to determine whether such facilities are operating in compliance with this Act. In general, inspections of facilities shall be conducted every 4 years. Noncertified facilities shall be inspected every 2 years. An inspection of any facility shall extend to all things therein that bear on whether food products are in compliance with this Act. Within 24 hours of inspection, a report shall be issued in writing setting forth any conditions or practices observed which indicate that either processing controls are inadequate to prevent or minimize food safety hazards or that any food from such facility is unsafe for human consumption, adulterated, or misbranded under this Act.

Section 105. Reinspection fee applicable to facilities.

Adds a new section 741A where the Secretary shall assess and collect fees from each facility that commits a violation of any requirement of this Act relating to food, including good manufacturing practices because such violation requires additional inspection by the Food and Drug Administration.

Section 106. Food facility certification program.

Adds a new section 420 where the Secretary shall establish a voluntary program for the certification of a facility as being in compliance with the applicable requirements of this Act. Any facility may apply to be certified. The Secretary shall make available to the public through the FDA Web site a list of each facility that is certified under this section and the date on which it was certified. The certification for a facility shall be in effect for 2 years from the date of approval. Certification is contingent upon successful completion of an inspection.

Section 107. Testing of food shipments; accredited laboratories.

Adds a new section 421for testing of food shipments.

(a) Testing in Non-Certified Facilities. Before introducing or delivering for introduction into interstate commerce any shipment of food, a facility that is engaged in manufacturing, packaging, processing, or holding such food that is not certified shall arrange for an accredited laboratory to conduct sampling and testing of such shipment to ensure compliance with applicable food safety standards. Test results shall be simultaneously submitted to the Secretary and the owner of such a facility.

(b) Testing in Certified Facilities. A certified facility shall arrange for an accredited laboratory to conduct, on a periodic basis specified by the Secretary, sampling and testing and report results to the Secretary and to the owner of such facility.

(c) Accreditation of Laboratories. The Secretary shall accredit laboratories for the purpose of conducting sampling and testing of certified and non-certified facilities. Not later than 1 year after the date of enactment, the Secretary shall establish and publish standards for laboratories to accredit or deny accreditation. The Secretary shall assess and collect an annual fee specified by the Secretary.

Section 108. Safe and secure food importation program.

Adds a new Section 805 for expedited movement of food through the importation process if each facility involved in the production, manufacture, processing, packaging, and holding of the food is certified and has been determined to be in compliance with food safety and security guidelines developed by the Secretary.

Subtitle B—Intervention

Section 111. Imports and commercial food importation through specific ports of entry.

Adds a new section 422. Beginning on a date not later than 5 years after enactment, food shall only enter the United States through a port of entry that is located in a metropolitan area with a Federal food-testing laboratory, unless each facility that has manufactured, processed, packed, and held the food is certified.

Section 112. Research on testing techniques for use in inspections of imported food safety; priority regarding detection of intentional adulteration.

Amends Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) by adding a new section (p) entitled "Research on Testing Techniques for Use in Inspection for Imported Food Safety". Requires the Secretary to provide research on testing techniques and sampling methods for use in food inspections.

Section 113. Notification, nondistribution, and recall of adulterated or misbranded articles of food.

Adds a new Section 423 to the Federal Food, Drug, and Cosmetic Act.

(a) Notification to Secretary of Violation. A person (other than a household consumer or other individual who is the intended consumer of an article of food) that has reason to believe that an article of food when introduced into or while in interstate commerce is adulterated or misbranded in a manner that, if consumed, may result in illness or injury shall notify the Secretary of the identity and location of the article.

(b) Recall and Consumer Notification. The Secretary shall provide all appropriate persons with an opportunity to cease distribution of the article, notify all persons, and recall the article, and in consultation with the Secretary, provide notice of the finding of the Secretary to all consumers to which the article was, or may have been distributed, and notify State and local public health officials. Under (b)(2) *Mandatory Actions*, if the appropriate person does not carry out the actions in the above paragraph, the Secretary shall issue an order requiring the person to immediately cease distribution of the article, and to immediately make the notification. The Secretary may take control or possession of the article.

(c) Hearings on Orders. The Secretary shall provide a person subject to an order with an opportunity for a hearing, within 2 days of issuance of an order, on the actions required by the order and any reasons why the article of food that is the subject of the order should not be recalled.

(d) Post-Hearing Recall Orders. After providing an opportunity for a hearing, the Secretary may, as the Secretary determines to be necessary to amend the order, require a recall of the article, specify a timetable during which the recall shall occur, require periodic reports to the Secretary describing the progress of the recall, and provide notice of such recall to consumers to which the article was, or may have been, distributed.

Subtitle C—Response

Section 121. Civil penalties relating to food.

Adds a new Section 303A to the Federal Food, Drug, and Cosmetic Act. The Secretary may assess against a person that commits an act prohibited by section 301 with respect to an article of food, a civil penalty for each such an act of not more than $100,000 in the case of an individual and $500,000 in the case of any other person. Each prohibited act described and each day during which the act continues shall be considered a separate offense.

Subtitle D—Miscellaneous

Section 131. Labeling requirement for meat, poultry products, and seafood that contain carbon monoxide.

Adds a new paragraph (t) to Section 201 of the Federal Food, Drug, and Cosmetic Act.

Meat, poultry, or seafood intended for human consumption that includes carbon monoxide to affect coloring shall bear a label that is prominently and conspicuously displayed for the ordinary person to understand.

The label shall state, "CONSUMER NOTICE: Carbon monoxide has been used to preserve the color of this product. Do not rely on color or the "use or freeze by" date alone to judge the freshness or safety of the product."

The labeling requirement above will apply to food labeled on or after the date that is 30 days after enactment of the legislation.

After 5 years, the Secretary has the discretion to issue alternative labeling requirements that are shown to be adequate and effective in preventing consumer deception and other harms related to the conditions of use of carbon monoxide.

Section 132. Food substances generally recognized as safe.

Amends Section 409 of the Federal Food, Drug, and Cosmetic Act by adding a new paragraph (k). The Secretary shall publish in the Federal Register a request for a substance to be determined as a generally recognized as safe (GRAS) food substance. Not later than 90 days after the date of publication of a notice concerning a GRAS food substance, the Secretary shall determine whether the substance is considered generally recognized as safe. Such determination by the Secretary shall be published in the Federal Register.

Section 133. Country of origin labeling; disclosure of source ingredients

Amends Section 403 by adding a new paragraph (z). In the case of a processed food, if the labeling of the food fails to identify the country in which the final processing of the food occurs and the Web site for the manufacturer of the food fails to identify the country (or countries) of origin for each ingredient, the food will be deemed misbranded.

In the case of non-processed food, if the labeling of the food fails to identify the country of origin of the food and the Web site for the original packer of the food fails to identify the country of origin, the food shall be deemed misbranded.

Section 134. New food and animal feed export certification fee to improve the ability of United States firms to export their products.

Creates a new Section 741D in the Federal Food, Drug, and Cosmetic Act granting the Secretary the authority to impose a fee for the issuance of export certificates for foods and animal feeds in cases where exportation is restricted without such a certificate.

Title II - Drug and Device Safety

Section 201. Registration fee applicable to producers of drugs and devices.

Adds a new section 736C to the Federal Food, Drug, and Cosmetic Act. The Secretary shall assess and collect an annual registration fee for domestic and foreign drug and device establishments for the purpose of defraying the costs of inspecting establishments registered to ensure that such establishments are in compliance with requirements of this Act. The Secretary shall determine the amount of the fee for drug and device establishments.

Section 202. Inspection of producers of drugs, active pharmaceutical ingredients, devices, and device parts.

Amends subsection (p) of section 301 to require an initial inspection before the introduction or delivery for introduction into interstate commerce of any drug, active pharmaceutical ingredient, class II or III device, or device part to such a device, as determined by the Secretary.

Requires domestic and foreign drug and device establishments to be inspected every 2 years. Current law requires only domestic drug and device establishments to be inspected every 2 years.

Section 203. Documentation for admissibility of drug imports.

Amends Section 801 by adding at the end that a drug shall only enter the United States, other than only for personal use, through a port of entry that is located in a metropolitan area with a Federal testing laboratory, unless the party offering that drug for import provides the

Secretary, at the time of offering the drug for import, documentation demonstrating compliance with applicable requirements pertaining to identity, strength, quality, purity, approval, listing, labeling, and registration.

Section 204. Origin of ingredients.

Amends Section 501(a)(2) by adding a new subsection (D) that allows the Secretary to deem a drug adulterated if, upon request, the manufacturer of the ingredient and of each drug that contains that ingredient does not have adequate documentation to establish where the ingredient was made, that the ingredient is not adulterated or misbranded, that the ingredient will perform in accordance with specifications, and is not contaminated.

Section 205. Testing for drug purity and identity.

Amends Section 501(a)(2) by adding new subsections (E) and (F). Subsection (E) allows the Secretary to deem a drug adulterated unless each manufacturer of the finished dosage form and active ingredients contained in or consisting of that drug verifies its product's purity and identity using scientifically sound and appropriate methods of sufficient analytical precision.

Subsection (F) allows the Secretary to deem a drug adulterated unless each manufacturer of an active pharmaceutical ingredient contained in or consisting of that drug periodically evaluates its ingredient's impurity profile to verify that it remains substantially similar to or better than the profile of the lot (or lots) used in the clinical studies and/or toxicological evaluation.

Section 206. Country of origin labeling.

Amends Section 502 by adding at the end language that allows the Secretary to deem misbranded a drug or device if its labeling fails to identify the country (or countries) which is the source of the active pharmaceutical ingredient in whole or in part and of its place of manufacture in the case of a drug, or the country of manufacture, in the case of a device. In the case of a drug, the Web site of the manufacturer of the drug does not list the country of origin for any drug ingredient of such drug.

Section 207. Recall authority for drugs.

Adds a new Section 568 granting the Secretary the same recall authority with respect to drugs as the Secretary has with respect to devices.

Section 208. Destruction of adulterated, misbranded or counterfeit drugs offered for import.

Amends section 801(a) that grants the Secretary the authority to destroy any product that is refused admission if (1) it appears to pose a risk of injury or death, or (2) has a value of less than $2,000, as determined by the Secretary.

Section 209. Administrative detention of drugs that appear to violate the law.

Amends Section 304(g) to grant the Secretary the same authority for detention of drugs as is currently available for devices.

Section 210. Civil money penalties for violative drugs and devices and improper import entry filings.

Amends Section 303. Any person who violates a requirement of this Act that relates to drugs and devices for human use shall be liable for a civil penalty not to exceed $100,000 per violation. Each day during which a violation continues shall be considered a separate violation.

Any person who knowingly reports or enters false data documents related to the introduction of drugs and devices in interstate commerce shall be liable to the United States for a civil penalty not to exceed $150,000. Each act of reporting or entering false data shall be considered a separate violation.

Title III—Cosmetic Safety

Section 301. Registration of cosmetic facilities.

Section 301 requires the Secretary, by regulation, to require any facility engaged in manufacturing, processing, packing, or holding of cosmetics to register annually. These facilities will be subject to a $2,000 registration fee. The Secretary shall, by regulation, require cosmetic manufacturing facilities to report all anticipated and unanticipated serious adverse events. The Secretary shall also, by regulation, require that cosmetic facilities comply with good manufacturing practices.

Title IV—Miscellaneous

Section 401. Registration and fee for commercial importers of food, drugs, devices, and cosmetics.

Section 401 requires importers of food, drugs, devices, and cosmetics to register with the Secretary. Importers of food, drugs, devices, and cosmetics are required to pay an annual registration fee of $10,000.

Section 402. Unique identification number for food, drug, and device facilities and establishments.

Section 402 requires the Secretary to issue a unique identification number to each registered food, drug, device, or cosmetic facility not later than 1 year after enactment.

Section 403. Dedicated foreign inspectorate.

Section 403 requires the Secretary to establish and maintain a corps of inspectors dedicated to inspections of foreign food, drug, device, and cosmetics facilities and establishments at a frequency at least equivalent to the domestic inspection rate.

Section 404. Continued operation of field laboratories.

Section 404 prohibits the Secretary from terminating or consolidating any of the 13 field laboratories that were operated by the FDA Office of Regulatory Affairs as of January 1, 2007, or any of the 20 FDA district offices. The Secretary is required to submit a reorganization plan involving these offices to the Comptroller General of the Government Accountability Office and Committees of jurisdiction. The Comptroller General shall study the cost effectiveness of the reorganization plan and its impact on the safety of food, drug, and other products regulated by under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. The reorganization plan shall be considered a major rule and submitted for Congressional review by the Committees of jurisdiction.

Section 405. False or misleading reporting to FDA.

Section 405 prohibits the submission of any report, with respect to devices, food, drug, or biological product that is false or misleading.

Section 406. Application to biological products.

Section 406 states that the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall also apply to biological products.

Section 407. Limitation to commercial importation.

Section 407 states that the Act does not apply to importation other than commercial importation.