



September 29, 2010

Discussion Draft of Drug Safety Legislation

SECTION-BY-SECTION SUMMARY

Committee on Energy and Commerce

Section 1. Short Title

The short title has not yet been designated.

Section 2. Table of Contents

Section 2 provides the table of contents.

TITLE I – PREVENTION

Section 101. Registration of Producers of Drugs; Applicable Fee.

Section 101 requires excipient manufacturers to register with the Food and Drug Administration (FDA). (Excipients are substances used to dilute or carry the active pharmaceutical ingredient in a drug or to give suitable consistency or form to the drug.)

Section 101 amends section 510 of the Federal Food, Drug, and Cosmetic Act (FFDCA) with respect to a variety of registration elements. It requires drug producers to provide FDA with a qualitative and quantitative listing of each of the ingredients of a listed drug and enables FDA to change the frequency with which such information must be provided. It authorizes FDA to suspend the registration of a drug establishment for a violation of the FFDCA or for the knowing or repeated making of an inaccurate or incomplete statement or submission of information. FDA can also cancel a registration if it is not updated as required, if it contains false, incomplete, or inaccurate information, or if the registration fee is not paid within 30 days of its due date.

Section 101 requires FDA to assess and collect an annual registration fee through fiscal year 2015 to defray the costs of drug safety activities. The discussion draft leaves blank the amount of such fee.

Section 102. Drug Supply Quality and Safety.

Section 102 requires drug manufacturers to implement an effective quality system that ensures compliance with good manufacturing practices. Such system must ensure that all operations relating to manufacturing drugs, including those manufactured by others, are appropriately designed, approved, conducted, monitored, and corrected. The quality system also must include risk management procedures that ensure effective risk assessment, control, and communication.

The risk assessment procedures must address all relevant factors throughout the supply chain, including, original source materials and their origin, on-site audits, current good manufacturing practice requirements, and methods to detect or exclude potentially risky substances. In addition, manufacturers must maintain records of these procedures for at least two years and permit FDA to inspect them at any time.

Beginning two years after enactment of this Act, manufacturers must maintain, and provide in electronic form to FDA upon request, adequate information establishing where a drug and its raw materials were produced, including all information on preceding producers, manufacturers, distributors, and shippers. The information also must establish that the drug was manufactured and distributed under conditions ensuring its identity, strength, quality, and purity.

Section 103. Inspection of Producers of Drugs.

Section 103 amends section 510 of the FFDCA to require the Secretary of the Department of Health and Human Services (HHS) to inspect every establishment (domestic and foreign) engaged in the manufacture, propagation, compounding, or processing of a finished dosage form drug or of an active pharmaceutical ingredient at least once every two years subsequent to registration. The Secretary may reduce this inspection schedule to once every four years, if FDA determines, in light of the risks presented by a particular establishment, that such a reduced schedule is appropriate (based on factors the Secretary establishes through guidance). The Secretary must conduct an inspection of a facility before the drug is introduced into interstate commerce if the active ingredient is new to the drug or if the drug has undergone a major change requiring prior approval, unless the Secretary determines such inspection is not necessary based on the inspection history of the establishment.

Section 103 also amends section 510 of the FFDCA to clarify that the Secretary may inspect every establishment engaged in the manufacture, propagation, compounding, or processing of an excipient of a drug to the same extent as it can inspect establishments engaged in such processes regarding any other drug.

Section 103 requires the Secretary to submit an annual report to Congress on the funding dedicated to inspections, and on the number of establishments for which the Secretary modified the inspection schedule based on risk.

Section 103 requires the Secretary to establish information systems that can assist the Secretary in assessing risk and for conducting surveillance. The Secretary must begin the implementation of this system within 3 years of the enactment of this Act, and that same year, GAO must submit a report to Congress on the Secretary's risk-based process.

Section 104. Prohibition Against Delaying, Limiting, or Refusing Inspection.

Section 104 amends section 501 of the FFDCA to prohibit facilities from delaying, limiting, or refusing entry for inspection by an officer or employee of the Secretary.

Section 105. Clarification of Inspection Authority Related to BIMO and IRB Inspections.

Section 105 amends section 704 of the FFDCA to clarify that certain officers or employees designated by the Secretary are authorized to enter and inspect the premises of a clinical investigator, sponsor, monitor, contract research organization, site management organization, institutional review board, or other person that oversees, initiates, or conducts a clinical investigation subject to section 505(i) of the FFDCA, or a postmarket study or clinical trial subject to section 505(k) or 505(o) of the FFDCA, and any establishment associated with such clinical investigation, postmarket study, or clinical trial.

Section 106. Notification, Nondistribution, and Recall of Adulterated or Misbranded Drug Products.

Section 106 requires persons that are required to register with the Secretary to notify the Secretary as soon as practicable of the identity and location of a drug that has entered interstate commerce that the person

has reason to believe is adulterated or misbranded and may result in illness or injury to humans or animals.

Section 106 permits the Secretary to request any person who distributes a drug that the Secretary has reason to believe is adulterated, misbranded, or otherwise in violation of the FFDCa to voluntarily recall such article.

Section 106 permits the Secretary to issue an order requiring any person who distributes a drug to immediately cease distribution of such drug if the Secretary has reason to believe that the use or consumption of, or exposure to, the drug may result in illness or injury to humans or animals. The person subject to the order must immediately cease distribution and provide notification as provided by the order, and may appeal the order within 24 hours of its issuance and request an informal hearing. If after providing an opportunity for an informal hearing, the Secretary determines that the order should be amended to include a recall of the drug, the Secretary must amend the order to require a recall.

If the Secretary has credible evidence or information that a drug subject to a cease distribution order presents an imminent threat of serious adverse health consequences or death to humans or animals, the Secretary may issue an emergency recall order requiring any person who distributes such drug to immediately recall such drug. An informal hearing must be granted following the issuance of such a recall.

Section 107. Notification.

Section 107 authorizes the Secretary to require that regulated persons notify the Secretary of any of the following circumstances regarding a drug:

- The use of a drug or exposure to it may result in illness or injury to humans or animals;
- A significant loss or known theft of the drug;
- A reasonable probability that a drug has been or is being counterfeited;
- A manufacturer of a component or other material used in the manufacture of a drug repeatedly failed to ensure compliance with applicable quality systems requirements;
- Any incident causing a drug to be mistaken for, or its labeling applied to, another drug;
- Any contamination or significant change or deterioration in the drug after distribution, or any failure of a distributed lot to meet an established specification; or
- Any other type of information the Secretary deems necessary to protect public health.

Section 107 defines a “regulated person” to be one who is required to register under section 510, 801(r), or 801(s) of the FFDCa, a wholesale distributor of a drug product, or any other person that distributes drugs except for retail sale.

Section 107 also authorizes the Secretary to share certain confidential information relating to a drug with any federal agency, state, local, or foreign government, but specifies that such information may not be publicly disclosed. The Secretary may, however, disclose certain confidential information to the public if the Secretary determines that such disclosure is necessary to protect the public health.

TITLE II – RESPONSE

Section 201. Administrative Detention.

Section 201 amends section 304 of the FFDCa to allow FDA officers or employees to order the detention of any drug if they have reason to believe it is in violation of any provision of this Act. Such detention

may be up to 20 days, or up to 60 days if the Secretary determines the longer period is required to institute an action. The Secretary must afford an opportunity for an informal hearing and must confirm or revoke the detention within 15 days of such hearing.

Section 202. Destruction of Adulterated, Misbranded, or Counterfeit Drugs Offered for Import.

Section 202 amends section 801 of the FFDCFA to authorize the Secretary of the Treasury to destroy, upon referral by the HHS Secretary, any drug that the HHS Secretary determines to pose a reasonable probability of causing significant adverse health effect or that is valued by the Treasury Secretary at \$2,000 or less. The HHS Secretary must provide for notice and an opportunity for an informal hearing with respect to such destruction. Such notice and opportunity for an informal hearing may occur after the destruction of the above-described drugs. However, for a drug that does not pose a reasonable probability of causing an adverse health effect and that is valued at more than \$2,000, the notice and opportunity for hearing must occur before the destruction of the drug.

Section 203. Criminal Penalties.

Section 134 amends section 303 of the FFDCFA to require any person who knowingly violates section 301 of the FFDCFA with respect to a drug to be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.

Section 204. Civil Penalties.

Section 204 amends section 303 of the FFDCFA to require that any person who violates a requirement of this Act that relates to drugs to be subject to a civil penalty of not more than \$500,000 for each such violation, and \$10 million for all such violations adjudicated in a single proceeding. Each such violation and each day during which such violation occurs is considered to be a separate offense.

Section 205. Seizure.

Section 205 amends section 304 of the FFDCFA to stipulate that with respect to seizure proceedings relating to drugs, such proceedings must conform to procedures in admiralty rather than procedures for civil asset forfeiture.

Section 205 also specifies the conditions under which proceedings pending in two or more jurisdictions may be consolidated.

Section 206. Asset Forfeiture.

Section 206 amends section 303 of the FFDCFA to provide for criminal and civil forfeiture of any property, real or personal, constituting or relating to the gross proceeds obtained directly or indirectly as a result of a violation, or a conspiracy to commit a violation, of section 301 of the FFDCFA relating to drugs.

TITLE III – IMPORTATION AND EXPORTATION

Section 301. Documentation for Admissibility of Imports.

Section 301 authorizes the Secretary to require, as a condition of admissibility, the submission of documentation or other information for a drug that is imported or offered for import into the United States.

Section 302. Registration for Commercial Importers; Fee.

Section 302 requires all importers of drugs to register with the FDA, to pay an annual registration fee in the amount of \$500, and to submit appropriate unique identifiers. (An importer that is also a registered

facility under section 101 of the Act is subject to only one such fee.) Each registered importer must comply with good importer practices, which the Secretary must establish through regulation. The Secretary may suspend an importer's registration, after notice and opportunity for an informal hearing, if the importer is found in violation of the FFDCA, or is found to have knowingly or repeatedly made inaccurate or incomplete statements or submissions of information related to the importation of drugs. The Secretary may cancel an importer's registration if, after notice, the Secretary determines that the registration was not updated correctly or otherwise contains false, incomplete, or inaccurate information. If the importer's registration is updated or corrected no later than 7 days after notice is provided, the Secretary may not cancel the importer's registration.

Section 303. Registration for Customs Brokers.

Section 303 requires all customs brokers with respect to the importation of drugs to register with the FDA in a form and manner specified by the Secretary and to submit appropriate unique identifiers as a condition of registration. The Secretary may cancel a broker's registration if, after notice, the Secretary determines that the registration was not updated correctly or otherwise contains false, incomplete, or inaccurate information. If the registration is updated or corrected no later than 7 days after notice is provided, the Secretary may not cancel the registration. Section 303 also requires customs brokers, upon request, to permit FDA to inspect their facilities.

Section 304. Exportation Certificate Program.

Section 304 authorizes the Secretary to impose a fee for the issuance of export certificates for a drug. Such fee may not exceed such amount as the Secretary determines is reasonably related to the cost of issuing certificates with respect to the export of a drug.

Section 305. Extraterritorial Jurisdiction.

Section 305 establishes extraterritorial federal jurisdiction over any violation of this Act relating to any drug intended for import into the United States or any act in furtherance of the violation that has been committed in the United States.

Section 306. Dedicated Foreign Inspectorate.

Section 306 requires the Secretary to establish and maintain inspectors dedicated to inspections of foreign drug facilities and establishments.

TITLE IV – MISCELLANEOUS

Section 401. Unique Identification Number for Establishments, Importers, and Customs Brokers.

Section 401 requires that a person required to register as a drug establishment pursuant to section 510 of the FFDCA, and importers and custom brokers required to register pursuant to section 801 of the FFDCA submit, at the time of registration, a unique identifier for the drug establishment or the principal place of business of the importer or custom broker. The Secretary is authorized to specify (through guidance) the unique numerical identifier system to be used. In developing such guidance, with respect to importers and customs brokers, the Secretary is required to consult with the Commissioner responsible for Customs and Border Protection and take into account the utilization of existing unique identification schemes and compatibility with customs automated systems. The Secretary is required to refuse admission of an imported drug into the United States for interstate commerce unless the appropriate unique identifiers are provided for such drug.

Section 402. Country of Origin Labeling.

Section 402 amends section 502 of the FDCA to require that the website of the manufacturer of a finished dosage form drug to list both the country of origin for each active pharmaceutical ingredient in the drug and the place of manufacture of its finished dosage form.

Section 403. False or Misleading Reporting to FDA.

Section 403 amends Section 301 of the FDCA to establish as a prohibited act, the submission of any report relating to a drug that is required by or under this Act that is false or misleading in any material respect.

Section 404. Subpoena Authority.

Section 404 grants the FDA Commissioner the power to issue subpoenas for the purpose of any hearing, investigation, or other proceeding respecting a violation of the FDCA, the Federal Anti-Tampering Act, and the Public Health Service Act relating to a drug; or to determine if a person is in violation of a specific provision of the FDCA, the Public Health Service Act, or the Federal Anti-Tampering Act relating to a drug. A subpoena may only be issued by a district director or an individual senior to the district director.

Section 405. Whistleblower Protections.

Section 405 grants protections for employees who refuse to violate this Act, or who disclose violations of this Act, or of the Public Health Service Act. No person who submits any information related to a drug, or any officer, employee, contractor, subcontractor, or agent may discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee in retaliation for assisting in any investigation regarding any conduct which the employee reasonably believes constitutes a violation of this Act that is related to a drug, or any other section of Federal law relating to the safety of a drug. Section 405 ensures an employee is entitled to all relief necessary against any retaliation by an employer.

Section 406. Rule of Construction.

Nothing in this Act or any amendment made by this Act shall be construed as affecting any authority or requirement relating to devices (as defined in section 201 of the FDCA).