

the Homeland Security Act of 2002 (Pub. L. 107–296), the Secretary of the Treasury has delegated all relevant Customs revenue authorities to the Secretary of Homeland Security who has, in turn, delegated them to the Commissioner of the Bureau of Customs and Border Protection (CBP or Customs). Thus, we are issuing this interim final rule jointly with the Secretary of Homeland Security.

Section 307 of the Bioterrorism Act amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 801(m) (21 U.S.C. 381(m)) and amending section 301 (21 U.S.C. 331). (In the regulation itself, which is codified in Title 21 of the Code of Federal Regulations, the Federal Food, Drug, and Cosmetic Act is referred to as “the act.” Thus, when the regulation is quoted in this preamble the term “the act” will be used to refer to the Federal Food, Drug, and Cosmetic Act. However, in this preamble we refer to the Federal Food, Drug, and Cosmetic Act as “the FD&C Act” in the preamble to distinguish it from the Bioterrorism Act.)

The Bioterrorism Act also requires FDA to issue regulations requiring certain food establishments to register with FDA (section 305), directs FDA to issue regulations regarding maintenance of certain records (section 306), and grants FDA the authority to administratively detain food (section 303). FDA has published proposed rules implementing section 305 of the Bioterrorism Act (68 FR 5378, February 3, 2003), section 303 of the Bioterrorism Act (68 FR 25242, May 9, 2003), and section 306 of the Bioterrorism Act (68 FR 25188, May 9, 2003). The interim final rule implementing the food facility registration requirements is published elsewhere in this issue of the **Federal Register**.

A. Current Process—Admissibility Determinations Under Section 801(a) of the FD&C Act

Section 801(a) of the FD&C Act sets out current standards and procedures for FDA review of imports under its jurisdiction. Section 801(a) provides for examination of imports and also authorizes FDA to refuse admission of imports that appear, from examination or otherwise, to be, *inter alia*, adulterated or misbranded. When an FDA-regulated product is imported, generally customs brokers submit entry information to CBP on behalf of the importers of record. CBP then provides entry information to FDA to enable admissibility decisions to be made. Under CBP authorities, entry of the

merchandise can be made up to 15 days after arrival.

CBP regulations provide for different kinds of entries. Commonly, merchandise is the subject of an entry for consumption or warehouse (*i.e.*, unrestricted, general use) under a basic importation and entry bond at the port of arrival. A warehouse entry is a CBP entry procedure as described in 19 CFR part 144. It allows imported product (with some restrictions) to be entered without payment of duty, provided it is kept in a bonded warehouse and not distributed. CBP authorities also allow for an Immediate Transportation or IT entry of merchandise for transportation under a custodial bond from the port of arrival to another port where the consumption or warehouse entry will be made or the product will be admitted into a foreign trade zone (FTZ) located outside of the port area. In addition, if the merchandise is going to an FTZ in the port area, FTZ admission documents are presented to CBP. Finally, a transportation and exportation (or T&E) entry may be filed if the merchandise is to be transhipped from the port of arrival through the United States to another port for export.

FDA currently receives electronic information about entries from CBP through CBP's ABI of the ACS. FDA receives this information through its Operational and Administrative System for Import Support (OASIS). The entry types currently transmitted through the ABI/ACS interface with OASIS include consumption entries and warehouse entries but not IT entries, T&E entries, or admissions into FTZs. The customs broker or self-filer electronically submits entry information to ABI/ACS, including: The identification of the product by the Harmonized Tariff Schedule (HTS) code; the entry type; the entry number (including both the ACS line number and the FDA line number); the arrival date; the port; the port of unloading; the carrier code; the vessel name and voyage, flight or trip number; importer and ultimate consignee; the quantity; value; country of origin; bill of lading or airway bill number; the manufacturer; the importer of record; and the ultimate consignee. The HTS codes are flagged to indicate which products will require FDA review; all FDA-regulated products are covered, not just foods. The additional information that is currently transmitted through the ABI/ACS interface to FDA includes: The FDA manufacturer; the FDA shipper, the FDA Country of Production (country of origin); the complete FDA product code; a description of the food in common business terms; the quantity for each FDA line, and, as “Affirmations

of Compliance,” information specific to certain products, such as the Food Canning Establishment (FCE) Number.¹ CBP regulations do not mandate electronic transmission of entry information; therefore, some entries are filed in paper. If a “paper” entry is filed, it is customary for CBP to require that copies of entry documentation be submitted to FDA. The entry documents contain the same information as the electronic filing, typically the information required on CBP's Entry/Immediate Delivery (CF3461), and a copy of the foreign invoice. The paper entries may be presented at the time of arrival or after.

After information is transmitted from ABI/ACS, OASIS performs additional validations on the data. If no corrections from the customs broker or self-filer are needed, it screens the entry information against FDA admissibility criteria. If the FDA electronic review determines that further evaluation of the information or article of food is not necessary, the system transmits a message back through the FDA/CBP interface that the article of food “may proceed without FDA examination.” If further evaluation is necessary, FDA staff will review the entry information and may request additional information necessary to make an admissibility determination or may examine or sample the product. Section 801(b) of the FD&C Act provides for the release of FDA regulated products to the importer or owner, under bond, before the FDA admissibility decision is made. Accordingly, FDA examination may take place at a location to which the product has been moved. Because there are no restrictions on movement, the product may be at the border, within the confines of a port, at a public storage facility in the vicinity of the importer, or at the ultimate consignee's warehouse. Finally, if the FDA electronic review indicates that the product appears “by examination or otherwise” to be subject to refusal of admission under section 801(a) of the FD&C Act (*e.g.*, appears to be adulterated or misbranded), the FDA reviewer will evaluate the entry information based on FDA guidance, take appropriate action, and notify the importer as well as the customs broker.

Under current laws and regulations, FDA may receive the information about some food imports some days after the food has arrived in the United States,

¹ Affirmations of Compliance are data elements that a customs broker or self-filer currently uses when transmitting certain information to FDA through ABI/ACS to OASIS. Each provides a mechanism to indicate (or affirm) compliance with a specific FDA regulatory requirement.