

article was shipped.” (68 FR 5437). However, in drafting the interim final rule, we have realized that this description was not written in a way that was useful in identifying the shipper in the case of food imported by international mail. Accordingly, we have revised the description of the “shipper” and included it in the definitions to make it easier to find.

The definition is based on the description of “shipper” used by CBP in their proposed rule, “Required Advance Electronic Presentation of Cargo Information,” published in the **Federal Register** on July 23, 2003 (68 FR 43574 at 43577), which is similar to, but clearer than, the description we used in the preamble to the proposed prior notice rule.

(Interim final rule) The interim final rule (§ 1.276(b)(12)), defines “shipper” as “the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail to the United States.”

13. United States (§ 1.267(b)(13))

Although the term appears in several places in section 801(m) of the FD&C Act itself, the proposed rule did not contain a definition of “United States.”

(Comments) A comment seeks clarification whether the prior notice regulation applies to food imported into Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other U.S. Territories.

(Response) This comment raises the question of what the term “United States” means for purposes of section 801(m) of the FD&C Act. In construing the prior notice provision of the Bioterrorism Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented? (“*Chevron* step one”) (*Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842 (1984)). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue (*Young v. Community Nutrition Institute*, 476 U.S. 974, 980 (1986)). If Congress has spoken directly and plainly, the agency must implement Congress’s unambiguously expressed intent (*Chevron*, 467 U.S. at 842–843). If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of “United States,” FDA may define “United States” in a reasonable fashion (“*Chevron* step two”); (*Chevron*, 467 U.S. at 842–843; *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000)). The agency has determined that, in enacting section 801(m) of the FD&C Act, Congress did

not speak directly and precisely to the meaning of “United States.”

The FD&C Act does apply to Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other U.S. Territories. Section 201(a)(1) of the FD&C Act (21 U.S.C. 321 (a)(1)) defines the term “State” to mean any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico. The term “Territory” is defined to mean any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone, section 201(a)(2) of the FD&C Act (21 U.S.C. 321(a)(2)). However, the terms “State” and “Territory” are not used in section 801(m) of the FD&C Act.³ Instead, section 801(m) of the FD&C Act deals with “articles imported or offered for import into the United States,” (section 801(m)(1)).

The term “United States” is not defined in the FD&C Act’s general definitions in section 201. Nor is it defined in section 801(m) of the FD&C Act. It is defined for purposes of section 702(a) of the FD&C Act (21 U.S.C. 372(a)), which provides:

In the case of a food packed in the Commonwealth of Puerto Rico or a Territory [FDA] shall attempt to make inspection of such food at the first point of entry within the United States * * *. For the purposes of this subsection, the term “United States” means the States and the District of Columbia.

This definition in section 702(b) seems to imply that, in other places in the FD&C Act, the term “United States” would include all Territories. However, in section 801(m) of the FD&C Act, the term “United States” appears as part of the phrase “for purposes of enabling inspection of such [food] articles at the ports of entry into the United States” (emphasis added). As defined by CBP, “port of entry” means ports within the part of the United States that has been denominated as the “Customs territory of the United States.” (19 CFR 101.1 and 101.3). Notably, though, the Territories are not considered part of the Customs territory of the United States. CBP defines “Customs territory of the United

States” to “include[] only the States, the District of Columbia, and Puerto Rico.” (19 CFR 101.1).

Because of this reference to “the ports of entry into the United States,” FDA has concluded that the term “United States” is best interpreted in section 801(m) of the FD&C Act to be the Customs territory of the United States and include only the 50 States, the District of Columbia, and Puerto Rico, but not the U.S. Territories and possessions. Defining the “United States” to be the Customs territory of the United States will maximize FDA’s ability to coordinate prior notice with the CBP entry process, as CBP entry is made for articles from the Territories when they arrive in the Customs territory of the United States. Thus, section 801(m) of the FD&C Act does not apply to articles of food imported or offered for import into Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other U.S. Territories; section 801(m) does apply, however, when articles of food are imported or offered for import from the Territories into the United States as defined by § 1.276(b)(11) of the interim final rule.

(Interim final rule) The interim final rule (§ 1.276(b)(13)), defines “United States” to mean the Customs territory of the United States, *i.e.*, the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico, but not any other part of the United States.

14. You (§ 1.276(b)(14))

The proposed rule defined “you,” based on who was authorized to submit prior notice, as “the purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer or the arriving carrier * * * or, if known, the in-bond carrier.

(Comments) No comments were received concerning the definition of “you.” However, comments were received about who may submit prior notice.

(Response) Discussion of those comments and our responses are found in the section “Who is Authorized to Submit Prior Notice?” FDA decided, based on revisions to who may submit prior notice, to revise the definition of “you.” The interim final rule clarifies that “you” means the persons (*i.e.*, individuals and firms) submitting or transmitting the prior notice. The submitter is responsible for the prior notice. The persons who send the prior notice are transmitters. If the submitter sends the prior notice, he or she is both

³ The terms “State” and “Territory” are key to the FD&C Act’s definition of “interstate commerce,” which is, in turn, key to many of the FD&C Act’s general inspection and enforcement provisions, see, *e.g.*, sections 301, 304, and 704 (21 U.S.C. 331, 334, and 374). However, while articles that “are imported or offered for import into the United States,” section 801(m)(1) of the FD&C Act, are in “interstate commerce,” see, *e.g.*, *U.S. v. 2,998 Cases* * * * *First Phoenix Group, Ltd.*, 64 F.3d 984 (5th Cir. 1995), the term “interstate commerce” does not appear in section 801(m).