

are subject to all of the regulations in this subpart.”

FDA also is proposing in § 1.226(h) to exempt facilities that are regulated exclusively, throughout the entire facility, by USDA under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*). Such facilities include meat and poultry slaughterhouses. This section complies with section 315 of the Bioterrorism Act entitled “Rule of Construction,” which states that nothing in title III of the Bioterrorism Act, or an amendment made by title III, shall be construed to alter the jurisdiction between USDA and the U.S. Department of Health and Human Services under applicable statutes and regulations.

FDA is proposing in § 1.226 that facilities that are jointly regulated by FDA and USDA will be required to register under this rule because they are under FDA’s jurisdiction as well as that of USDA. Examples of facilities jointly regulated by FDA and USDA include slaughter facilities that slaughter cattle and deer, and food processing facilities that process meat and nonmeat products, such as frozen T.V. dinners containing both meat, which is regulated by USDA, and fish, which is regulated by FDA.

As specified in the Bioterrorism Act, FDA also is proposing to exempt several other facilities from the registration requirement. These facilities, which are discussed in the definitions section, include farms (§ 1.226(b)); retail facilities (§ 1.226(c)); restaurants (§ 1.226(d)); and nonprofit food facilities in which food is prepared for, or served directly to, the consumer (§ 1.226(e)).

### 3. What Definitions Apply to This Subpart? (Proposed § 1.227)

As specified in proposed § 1.227, the following definitions are used throughout the proposed rule:

a. *The act.* The proposed rule (§ 1.227(a)) defines “the act” as the Federal Food, Drug, and Cosmetic Act. The proposed rule applies the definitions of terms in section 201 of the act (21 U.S.C. 321) to such terms in the proposed rule.

b. *Calendar day.* FDA is proposing in § 1.227(c)(1) to define “calendar day” as every day shown on the calendar. This term includes weekend days.

c. *Facility.* FDA is proposing in § 1.227(c)(2) to define a “facility” as “any establishment, structure, or structures under one management at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes,

packs, or holds food for consumption in the United States. Individual homes are not facilities if the food that is manufactured/processed, packed, or held in the home does not enter commerce.” In response to comments that FDA received during its early outreach efforts, FDA is clarifying in the proposed rule that a facility is not limited to one building, but can consist of several contiguous structures.

The definition of “facility” also specifies that a facility must be under one management. This means that, for purposes of the proposed rule, a single building may house distinct facilities if they are under separate management. If a facility is under joint management of two or more companies, the joint management arrangement is considered one management.

A mixed-type facility performs activities of a facility that is ordinarily required to register and activities of a facility that is ordinarily exempt, such as a farm or retail facility. In order to determine whether a mixed-type facility must register, FDA will consider whether the activity that would require registration is merely incidental to the activities of an exempt facility. If these activities are merely incidental, the facility need not register. For further clarification, see the discussion of the definitions of “farm,” “retail facility,” and “restaurant” that follow.

i. *Domestic facility.* FDA is proposing in § 1.227(c)(2)(A) to define “domestic facility” consistent with the definition of “State” in section 201(a)(1) of the act (21 U.S.C. 321(a)(1)). That is, FDA is proposing to define a domestic facility as one that is located in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

ii. *Foreign facility.* FDA is proposing in § 1.227(c)(2)(ii) to define a foreign facility as a facility other than a domestic facility that manufactures, processes, packs, or holds food for consumption in the United States.

d. *Farm.* FDA is proposing in § 1.227(c)(3) to define “farm” in part as “a facility in one general physical location devoted to the growing of crops for food, the raising of animals for food (including seafood), or both.” A farm may consist of contiguous parcels of land, ponds located on contiguous parcels of land, or, in the case of netted or penned areas located in large bodies of water, contiguous nets or pens. Some examples of farms include: Apple orchards, hog farms, dairy farms, feedlots, or aquaculture facilities.

The definition of “farm” includes: (i) Facilities that pack or hold food, provided that all of the food used in

such activities is grown or raised on that farm or is consumed on that farm; and (ii) facilities that manufacture/process food, if all of the food used in such activities is consumed on that farm or another farm under the same ownership. “Farm” includes such facilities because they are activities incidental to farming that most farms engage in (e.g., holding and packing of harvested crops). Facilities that engage in manufacturing/processing, packing, or holding of food that is not described in the definition of “farm” must register because such activities are not activities that most farms engage in and are thus not included in the definition of “farm.”

A farm that manufactures/processes, packs, or holds food is not required to register with FDA, if all of the food used in such activities is consumed on that farm or another farm under the same ownership. For example, a farm that manufactures/processes animal feed from ingredients obtained off the farm for consumption by animals on the farm would be exempt because most farms that raise animals engage in this activity.

This definition does not extend to facilities that grow crops and raise animals and also manufacture/process food that is sold for consumption off the facility because such activities are not incidental to farming. For example, a facility that grows oranges and manufactures/processes them into orange juice for sale to a distributor would be required to register as a manufacturing/processing facility.

A facility could meet the definition of “farm” if all of the activities on the farm meet the description in § 1.227(c)(3)(i), (c)(3)(ii), or both. For example, one farm could meet the description in § 1.227(c)(3)(i) if all of the food packed or held on the farm was grown on that farm. A second farm could meet the description in § 1.227(c)(3)(ii) if all of the food manufactured/processed on the farm is consumed on that farm, even if some of the food was not grown or raised on the farm (e.g., animal feed processed on the farm using materials obtained off the farm and fed to cattle on that farm).

It should be noted that the proposed retail exemption also may apply to facilities that grow crops and raise animals. Thus, a facility that grows crops and raises animals and that also manufactures/processes, packs, or holds food and sells it directly to consumers would be exempt from registering as a retail facility under § 1.226(e), whether or not the food was all grown or raised on that facility. Similarly, a facility would be exempt as both a farm and a retail facility if it sold crops grown on