traceability plan must indicate the format and location of the records you are required to keep under this subpart, in accordance with § 1.1315(a)(1).

(h) *Public disclosure.* Records obtained by FDA in accordance with this subpart are subject to the disclosure requirements under part 20 of this chapter.

CONSEQUENCES OF FAILURE TO COMPLY

§ 1.1460 What consequences could result from failing to comply with the requirements of this subpart?

(a) *Prohibited act.* The violation of any recordkeeping requirement under section 204 of the FDA Food Safety Modernization Act, including the violation of any requirement of this subpart, is prohibited under section 301(e) of the Federal Food, Drug, and Cosmetic Act, except when such violation is committed by a farm.

(b) *Refusal of admission.* An article of food is subject to refusal of admission under section 801(a)(4) of the Federal Food, Drug, and Cosmetic Act if it appears that the recordkeeping requirements under section 204 of the FDA Food Safety Modernization Act (other than the requirements under subsection (f) of that section), including the requirements of this subpart, have not been complied with regarding such article.

UPDATING THE FOOD TRACEABILITY LIST

§ 1.1465 How will FDA update the Food Traceability List?

(a) When FDA tentatively concludes, in accordance with section 204(d)(2) of the FDA Food Safety Modernization Act, that it is appropriate to revise the Food Traceability List, we will publish a notice in the FEDERAL REGISTER stating the proposed changes to the list and the reasons for these changes and requesting information and views on the proposed changes.

(b) After considering any information and views submitted on the proposed changes to the Food Traceability List, FDA will publish a notice in the FEDERAL REGISTER stating whether we are making any changes to the list and the reasons for the decision. If FDA revises the list, we will also publish the revised list on our website.

(c) When FDA updates the Food Traceability List in accordance with this section, any deletions from the list will become effective immediately. Any additions to the list will become effective 2 years after the date of publication of the FEDERAL REGISTER notice announcing the revised list, unless otherwise stated in the notice.

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

Subpart A—General Provisions

Sec.

Subpart B—Human and Animal Foods

Subparts C–E [Reserved]

Subpart F—Caustic Poisons

Subpart G—Provisions Applicable to Specific Products Subject to the Federal Food, Drug, and Cosmetic Act

AUTHORITY: 15 U.S.C. 402, 409; 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374; 42 U.S.C. 7671 *et seq.*

SOURCE: 42 FR 15559, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 2.5 Imminent hazard to the public health.

(a) Within the meaning of the Federal Food, Drug, and Cosmetic Act an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent

injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held. The *imminent hazard* may be declared at any point in the chain of events which may ultimately result in harm to the public health. The occurrence of the final anticipated injury is not essential to establish that an *imminent hazard* of such occurrence exists.

(b) In exercising his judgment on whether an *imminent hazard* exists, the Commissioner will consider the number of injuries anticipated and the nature, severity, and duration of the anticipated injury.

§ 2.10 Examination and investigation samples.

(a)(1) When any officer or employee of the Department collects a sample of a food, drug, or cosmetic for analysis under the act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Department indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory. Only samples so designated by an officer or employee of the Department shall be considered to be official samples.

(2) For the purpose of determining whether or not a sample is collected for analysis, the term *analysis* includes examinations and tests.

(3) The owner of a food, drug, or cosmetic of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

(b) When an officer or employee of the Department collects an official sample of a food, drug, or cosmetic for analysis under the act, he shall collect at least twice the quantity estimated by him to be sufficient for analysis, unless:

(1) The amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated, in which case he shall collect as much as is available and reasonably accessible.

(2) The cost of twice the quantity so estimated exceeds $150.

(3) The sample cannot by diligent use of practicable preservation techniques available to the Food and Drug Administration be kept in a state in which it could be readily and meaningfully analyzed in the same manner and for the same purposes as the Food and Drug Administration's analysis.

(4) The sample is collected from a shipment or other lot which is being imported or offered for import into the United States.

(5) The sample is collected from a person named on the label of the article or his agent, and such person is also the owner of the article.

(6) The sample is collected from the owner of the article, or his agent, and such article bears no label or, if it bears a label, no person is named thereon.

In addition to the quantity of sample set forth in this paragraph, the officer or employee shall, if practicable, collect such further amount as he estimates will be sufficient for use as trial exhibits.

(c) After the Food and Drug Administration has completed such analysis of an official sample of a food, drug, or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded within the meaning of the act, or otherwise subject to the prohibitions of the act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise under the act based on the sample, a part of the sample, if any remains available, shall be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, except when:

(1) After collection, the sample or remaining part thereof has become decomposed or otherwise unfit for analysis, or

(2) The request is not made within a reasonable time before the trial of any case under the act, based on the sample to which such person or owner is a party. The person, owner, attorney, or