

§ 2.5

21 CFR Ch. I (4-1-03 Edition)

Subpart F—Caustic Poisons

2.110 Definition of ammonia under Federal Caustic Poison Act.

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

2.125 Use of ozone-depleting substances in foods, drugs, devices, or cosmetics.

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 introduc-

tion 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.