

**Food and Drug Administration, HHS**

**§ 1.99**

operations specified in the authorization have been completed, the original owner will be held responsible, unless the new owner has executed a bond and obtained a new authorization. Any authorization granted under this section shall supersede and nullify any previously granted authorization with respect to the article.

[42 FR 15553, Mar. 22, 1977, as amended at 54 FR 9033, Mar. 3, 1989]

**§ 1.97 Bonds.**

(a) The bonds required under section 801(b) of the act may be executed by the owner or consignee on the appropriate form of a customs single-entry or term bond, containing a condition for the redelivery of the merchandise or any part thereof upon demand of the collector of customs and containing a provision for the performance of conditions as may legally be imposed for the relabeling or other action necessary to bring the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic, in such manner as is prescribed for such bond in the customs regulations in force on the date of request for authorization. The bond shall be filed with the collector of customs.

(b) The collector of customs may cancel the liability for liquidated damages incurred under the above-mentioned provisions of such a bond, if he receives an application for relief therefrom, upon the payment of a lesser amount or upon such other terms and conditions as shall be deemed appropriate under the law and in view of the circumstances, but the collector shall not act under this regulation in any case unless the district director is in full agreement with the action.

**§ 1.99 Costs chargeable in connection with relabeling and reconditioning inadmissible imports.**

The cost of supervising the relabeling or other action in connection with an import of food, drugs, devices, or cosmetics which fails to comply with the Federal Food, Drug, and Cosmetic Act shall be paid by the owner or consignee who files an application requesting such action and executes a bond, pursuant to section 801(b) of the act, as amended. The cost of such supervision

shall include, but not be restricted to, the following:

(a) Travel expenses of the supervising officer.

(b) Per diem in lieu of subsistence of the supervising officer when away from his home station, as provided by law.

(c) The charge for the services of the supervising officer, which shall include administrative support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS-11/4 employee, except that such services performed by a customs officer and subject to the provisions of the act of February 13, 1911, as amended (sec. 5, 36 Stat. 901, as amended (19 U.S.C. 267)), shall be calculated as provided in that act.

(d) The charge for the service of the analyst, which shall include administrative and laboratory support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS-12/4 employee. The rate per hour equal to 266 percent of the equivalent hourly rate of regular pay of the supervising officer (GS-11/4) and the analyst (GS-12/4) is computed as follows:

	Hours
Gross number of working hours in 52 40-hr weeks	2,080
Less:	
9 legal public holidays—New Years Day, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day .....	72
Annual leave—26 d .....	208
Sick leave—13 d .....	104
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Total .....	384
Net number of working hours .....	1,696
Gross number of working hours in 52 40-hr weeks ..	2,080
Working hour equivalent of Government contributions for employee retirement, life insurance, and health benefits computed at 8½ pct. of annual rate of pay of employee .....	176
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Equivalent annual working hours .....	2,256
Support required to equal to 1 man-year .....	2,256
Equivalent gross annual working hours charged to Food and Drug appropriation ....	4,512

NOTE: Ratio of equivalent gross annual number of working hours charged to Food and Drug appropriation to net number of annual working hours 4,512/1,696=266 pct.

(e) The minimum charge for services of supervising officers and of analysts shall be not less than the charge for 1 hour, and time after the first hour shall be computed in multiples of 1

hour, disregarding fractional parts less than ½ hour.

## PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

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

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