



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 1005

[Docket No. FDA-2019-N-0011]

Office of Regulatory Affairs Division Director; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is revising its regulations to reflect changes to the Agency's organizational structure, including the reorganization of the Office of Regulatory Affairs (ORA). The revisions update addresses and replace references to the district officials with references to division officials. The rule does not impose any new regulatory requirements on affected parties. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Holli Kubicki, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20852, 240-402-4557.

SUPPLEMENTARY INFORMATION:

I. Background

ORA has reorganized to align field activities by FDA-regulated commodity (e.g., food, drugs, medical devices) or program area (e.g., imports). As a result, ORA division officials now perform certain duties such as those related to administrative appeals and informal hearings

previously performed by district officials. FDA regulations included numerous references to district officials. The revisions made by this rule update these references to division officials, but do not alter any substantive standards.

II. Description of the Technical Amendments

The regulations specified in this rule have been revised to replace references to the ORA Official, including “District Director” with references to the ORA division official, including “Division Director,” to reflect the ORA program alignment. In addition, we have updated the references to U.S. Customs and Border Protection, updated several addresses, and have made minor conforming amendments and grammatical changes as necessary to accommodate the new terminology. Finally, we have modified the hourly cost calculations related to overseeing reconditioning of imported products to bring them into compliance with the Federal Food, Drug, and Cosmetic Act to reflect 10 legal public holidays.

We are making these technical amendments to revise descriptions of FDA officials designated to perform certain functions. The amendments are technical and editorial in nature and should not be construed as modifying any substantive standards.

III. Notice and Public Comment

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (APA) (5 U.S.C. 553). Section 553 of the APA exempts “rules of agency organization, procedure, or practice” from proposed rulemaking (i.e., notice and comment rulemaking). 5 U.S.C. 553(b)(3)(A). Rules are also exempt when an agency finds “good cause” that notice and comment rulemaking procedures would be “impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. 553(b)(3)(B).

FDA has determined that this rulemaking meets the notice and comment exemption requirements in 5 U.S.C. 553(b)(3)(A) and (B). FDA's revisions make technical or non-substantive changes that pertain solely to the designation of FDA officials, and do not alter any substantive standard. FDA does not believe public comment is necessary for these minor revisions.

The APA allows an effective date less than 30 days after publication as "provided by the agency for good cause found and published with the rule" (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for the amendments to become effective on the date of publication of this action.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 1005

Administrative practice and procedure, Electronic products, Imports, Radiation protection, Surety bonds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 1005 are amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 373, 374, 379j-31, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107-188, 116 Stat. 594, 668-69; Pub. L. 111-353, 124 Stat. 3885, 3889.

2. Amend § 1.83 by revising paragraph (b) to read as follows:

§ 1.83 Definitions.

* * * * *

(b) The term *division director* means the director of the division of the Food and Drug Administration having jurisdiction over the port of entry through which an article is imported or offered for import, or such officer of the division as he or she may designate to act on his or her behalf in administering and enforcing the provisions of section 801(a), (b), and (c).

3. Revise § 1.90 to read as follows:

§ 1.90 Notice of sampling.

When a sample of an article offered for import has been requested by the division director, FDA shall provide to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample. Upon receipt of the notice, the owner or consignee shall hold such article and not distribute it until further notice from the division director or U.S. Customs and Border Protection of the results of examination of the sample.

4. In § 1.91, revise the second sentence to read as follows:

§ 1.91 Payment for samples.

* * * Billing for reimbursement should be made by the owner or consignee to the Food and Drug Administration division where the shipment was offered for import. * * *

5. Amend § 1.94 by revising the first sentence of paragraph (a), the second sentence of paragraph (b), and paragraph (c) to read as follows:

§ 1.94 Hearing on refusal of admission or destruction.

(a) If it appears that the article may be subject to refusal of admission or that the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the division director shall give the owner or consignee a written or electronic notice to that effect, stating the reasons therefor. * * *

(b) * * * If such application is not submitted at or prior to the hearing on refusal of admission, the division director shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

(c) If the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the division director may give the owner or consignee a single written or electronic notice that provides the notice of refusal of admission and the notice of destruction of an article described in paragraph (a) of this section. The division director may also combine the hearing on refusal of admission with the hearing on destruction of the article described in paragraph (a) of this section into a single proceeding.

6. Amend § 1.95 by revising the introductory text to read as follows:

§ 1.95 Application for authorization to relabel and recondition.

Application for authorization to relabel or perform other action to bring the article into compliance with the Federal Food, Drug, and Cosmetic Act or to render it other than a food, drug, device, or cosmetic may be filed only by the owner or consignee, and shall:

* * * * *

7. Amend § 1.96 by revising paragraph (a) introductory text and paragraphs (a)(3), (b), (c), and (d) to read as follows:

§ 1.96 Granting of authorization to relabel and recondition.

(a) When authorization of a proposal under § 1.95 is granted by the division director, the applicant shall be notified of authorization, in writing, which may include:

(3) That the operations are to be carried out under the supervision of an officer of the Food and Drug Administration or U.S. Customs and Border Protection, as appropriate;

* * * * *

(b) Upon receipt of a written request for extension of time to complete such operations, containing reasonable grounds therefor, the division director may grant such additional time as he or she deems necessary.

(c) An authorization may be amended upon a showing of reasonable grounds therefor and the filing of an amended application for authorization with the division director.

(d) If ownership of an article covered by an authorization changes before the operations specified in the authorization have been completed, the original owner will be held responsible, unless the new owner has executed a bond with U.S. Customs and Border Protection and obtained a new authorization from the Food and Drug Administration division director. Any authorization granted under this section shall supersede and nullify any previously granted authorization with respect to the article.

8. Revise § 1.97 to read as follows:

§ 1.97 Bonds.

(a) The bond requirements under section 801(b) of the Federal Food, Drug, and Cosmetic Act may be satisfied by the owner or consignee executing, on the appropriate U.S. Customs and Border Protection form, a single-transaction or continuous bond, containing a condition for the redelivery of the merchandise or any part thereof upon demand of U.S. Customs and Border Protection 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 U.S. Customs and Border Protection.

(b) U.S. Customs and Border Protection may cancel the liability for liquidated damages incurred under the above-mentioned provisions of such a bond, if U.S. Customs and Border Protection 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 U.S. Customs and Border Protection shall not act under this regulation unless the Food and Drug Administration division director is in full agreement with the action.

9. Amend § 1.99 by revising paragraphs (b), (c), and (d) to read as follows:

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

* * * * *

(b) Per diem in lieu of subsistence of the supervising officer when away from his or her 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 267 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 267 percent of the hourly rate of regular pay of a grade GS-12/4 employee. The rate per hour equal to 267 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:

Table 1 to paragraph (d)

	Hours
Gross number of working hours in 52 40-hr weeks	2,080
Less:	
10 legal public holidays--New Year's Day, Birthday of Martin Luther King, Jr., Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day	80
Annual leave--26 d	208
Sick leave--13 d	104
Total	392
Net number of working hours	1,688
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
Equivalent annual working hours	2,256
Support required to equal to 1 person-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 $4,512/1,688 = 267$ pct.

* * * * *

10. Amend § 1.101 to revise paragraphs (d)(2)(ii) and (iii) to read as follows:

§ 1.101 Notification and recordkeeping.

* * * * *

(d) * * *

(2) * * *

(ii) For human drug products, biological products, and devices regulated by the Center for Drug Evaluation and Research--Office of Drug Security, Integrity and Response, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

(iii) For devices--DRP2: Division of Establishment Support, Office of Regulatory Programs, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1423, Silver Spring, MD 20993.

* * * * *

11. Amend § 1.280 by revising the first sentence of paragraph (c) to read as follows:

§ 1.280 How must you submit prior notice?

* * * * *

(c) If FDA determines that FDA PNSI or the Operational and Administration System for Import Support (OASIS) is not working, FDA will post prominent notification and instructions at <https://www.access.fda.gov>--see log-in page. * * *

PART 1005--IMPORTATION OF ELECTRONIC PRODUCTS

12. The authority citation for part 1005 continues to read as follows:

Authority: 21 U.S.C. 360ii, 360mm.

13. Amend § 1005.11 by revising the second sentence to read as follows:

§ 1005.11 Payment for samples.

* * * Billing for reimbursement should be made by the owner or consignee to the Food and Drug Administration division where the shipment was offered for import. * * *

14. Amend § 1005.24 to revise paragraphs (b) and (c) to read as follows:

§ 1005.24 Costs of bringing product into compliance.

* * * * *

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

(c)(1) The charge for the services of the supervising officer, which shall include administrative support, shall be computed at a rate per hour equal to 267 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 (section 5, 36 Stat. 901, as amended (19 U.S.C. 267)), shall be calculated as provided in that act.

(2) The charge for the services of the analyst, which shall include administrative and laboratory support, shall be computed at a rate per hour equal to 267 percent of the hourly rate of regular pay of a grade GS-12/4 employee.

(3) The rate per hour equal to 267 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:

Table 1 to paragraph (c)(3)

	Hours
Gross number of working hours in 52 40-hour weeks	2,080
Less:	
10 legal public holidays--New Year's Day, Birthday of Martin Luther King, Jr., Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day	80
Annual Leave--26 days	208
Sick Leave--13 days	104
Total	392
Net number of working hours	1,688
Gross number of working hours in 52 40-hour weeks	2,080
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Equivalent annual working hours	2,256
Support required to equal to 1 person-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 (4,512/1,688) = 267 pct.

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Dated: July 30, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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