

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2002N-0276]

RIN 0910-AC40

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) published an interim final rule in the **Federal Register** of October 10, 2003 (68 FR 58894). The interim final rule requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States, to register with FDA by December 12, 2003. Due to several errors in §§ 1.231 and 1.232 (21 CFR 1.231 and 1.232), the interim final rule contains some incorrect information. This document corrects those errors.

DATES: Effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Melissa S. Scales, Center for Food Safety and Applied Nutrition (HFS-24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1720.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 10, 2003 (68 FR 58894), FDA published an interim final rule on Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and

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Response Act of 2002. Since that time, FDA has discovered that the interim final rule contains several errors.

First, FDA is correcting the phone number to which registration form requests and other technical questions should be directed. The appropriate phone numbers are 1–800–216–7331 or 301–575–0156.

Second, § 1.232 of the interim final rule contains several editorial errors. Section 1.232(d) currently states that each foreign facility must submit “the name, address, phone number, and emergency contact phone number of its U.S. agent (if there is no other emergency contact designated under § 1.233(c)).” To improve the clarity of this provision, FDA is also revising § 1.232(d). The reference to § 1.233(c) in this sentence is incorrect; the proper reference is to § 1.233(e). Also, the reference in § 1.232(g) to § 1.233(e) is incorrect; the proper reference is to § 1.233(j).

List of Subjects in 21 CFR Part 1

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

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART I—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.231 is amended by revising paragraph (b)(1) to read as follows:

§ 1.231 How and where do you register?

* * * * *

(b) * * *

(I) You must register using Form 3537. You may obtain a copy of this form by writing to the U.S. Food and Drug Administration (HFS-681), 5600 Fishers Lane, Rockville, MD 20857 or by requesting a copy of this form by phone at 1-800-216-7331 or 301-575-0156.

* * * * *

■ 3. Section 1.232 is amended by revising paragraphs (d) and (g) to read as follows:

§ 1.232 What information is required in the registration?

* * * * *

(d) For a foreign facility, the name, address, phone number, and, if no emergency contact is designated under § 1.233(e), the emergency contact phone number of the foreign facility's U.S. agent;

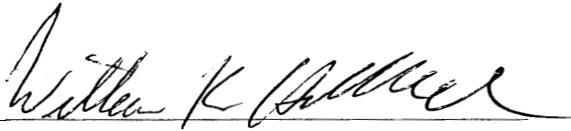
* * * * *

(g) Applicable food product categories as identified in § 170.3 of this chapter, unless you check either "most/all human food product categories," according to § 1.233(j), or "none of the above mandatory categories" because your facility manufactures/processes, packs, or holds a food that is not identified in § 170.3 of this chapter;

* * * * *

Dated: May 10, 2004

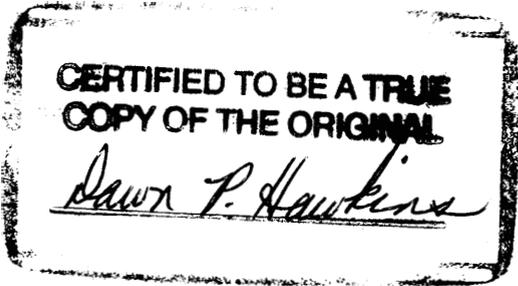
May 10, 2004.



William K. Hubbard,
Associate Commissioner for Policy and Planning.

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Dawn P. Hawkins