

because this Final Rule concerns agency procedure and practice and will not substantially affect the rights of non-agency parties.

10. The Commission is issuing this as a Final Rule without a period for public comment. Under 5 U.S.C. 553(b), notice and comment procedures are unnecessary where a rulemaking concerns only agency procedure and practice, or where the agency finds that notice and comment is unnecessary. This rule concerns only matters of internal agency procedure and will not significantly affect regulated entities or the general public.

#### List of Subjects in 18 CFR Part 375

Authority delegations (government agencies), Seals and insignia, Sunshine Act.

By the Commission.

**Nathaniel J. Davis, Sr.,**  
Deputy Secretary.

■ In consideration of the foregoing, the Commission amends part 375, chapter I, title 18, Code of Federal Regulations, as follows.

#### PART 375—THE COMMISSION

■ 1. The authority citation for part 375 continues to read as follows:

**Authority:** 5 U.S.C. 551–557; 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 791–825r, 2601–2645; 42 U.S.C. 7101–7352, 16451–16463.

■ 2. Add new § 375.315 to read as follows:

#### **§ 375.315 Delegations to the Director of the Office of Energy Policy and Innovation.**

The Commission authorizes the Director or the Director's designee to:

(a) Take appropriate action on:

(1) Any notice of intervention or motion to intervene, filed in an uncontested proceeding processed by the Office of Energy Policy and Innovation; and

(2) Applications for extensions of time to file required filings, reports, data and information and to perform other acts required at or within a specific time by any rule, regulation, license, permit, certificate, or order by the Commission.

(b) Undertake the following actions:

(1) Issue reports for public information purposes. Any report issued without Commission approval must:

(i) Be of a noncontroversial nature, and

(ii) Contain the statement, "This report does not necessarily reflect the views of the Commission," in bold face type on the cover;

(2) Issue and sign requests for additional information regarding

applications, filings, reports and data processed by the Office of Energy Policy and Innovation; and

(3) Accept for filing, data and reports required by Commission regulations, rules, or orders, or presiding officers' initial decisions upon which the Commission has taken no further action, if such filings are in compliance with such regulations, rules, orders or decisions and, when appropriate, notify the filing party of such acceptance.

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**BILLING CODE 6717–01–P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

#### 21 CFR Parts 106, 107, 312, and 803

[Docket No. FDA–2010–N–0010]

#### Change of Contact Information; Technical Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations to reflect changes in the contact information for the FDA Emergency Call Center. This action is editorial in nature and is intended to improve the accuracy of the agency's regulations.

**DATES:** This rule is effective June 11, 2010.

#### FOR FURTHER INFORMATION CONTACT:

Wayne Gorski, Office of Crisis Management, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 2300, Silver Spring, MD 20993–0002, 301–796–8248.

**SUPPLEMENTARY INFORMATION:** FDA is amending its regulations in 21 CFR parts 106, 107, 312, and 803 to reflect a change in the telephone and fax numbers for the FDA Emergency Call Center. The phone number will change from 301–443–1240 to 866–300–4374 on June 11, 2010. The fax number will change from 301–827–3333 to 301–847–8544. We have also amended the regulations to reflect that the new phone and fax numbers are for the "FDA Emergency Call Center".

Publication of this document constitutes final action on this change under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedures are unnecessary because FDA is merely updating nonsubstantive content.

#### List of Subjects

##### 21 CFR Part 106

Food grades and standards, Infants and children, Nutrition, Reporting and recordkeeping requirements.

##### 21 CFR Part 107

Food labeling, Infants and children, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

##### 21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

##### 21 CFR Part 803

Imports, Medical devices, 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 Chapter I is amended as follows:

#### PART 106—INFANT FORMULA QUALITY CONTROL PROCEDURES

■ 1. The authority citation for 21 CFR part 106 continues to read as follows:

**Authority:** 21 U.S.C. 321, 350a, 371.

■ 2. Section 106.120 is amended by revising paragraph (b) to read as follows:

#### **§ 106.120 New formulations and reformulations.**

\* \* \* \* \*

(b) The manufacturer shall promptly notify the Food and Drug Administration when the manufacturer has knowledge (as defined in section 412(c)(2) of the act) that reasonably supports the conclusion that an infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer may not provide the nutrients required by section 412(g) of the act and by regulations promulgated under section 412(a)(2) of the act, or when there is an infant formula that is otherwise adulterated or misbranded and that may present risk to human health. This notification shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office specified in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), contact the FDA Emergency Call Center at 866–300–4374. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to

the appropriate Food and Drug Administration district office specified in part 5, subpart M of this chapter.

## PART 107—INFANT FORMULA

■ 3. The authority citation for 21 CFR part 107 continues to read as follows:

**Authority:** 21 U.S.C. 321, 343, 350a, 371.

■ 4. Section 107.50 is amended by revising paragraph (e)(2) to read as follows:

### § 107.50 Terms and conditions.

\* \* \* \* \*

(e) \* \* \*

(2) The manufacturer shall promptly notify FDA when the manufacturer has knowledge (as defined in section 412(c)(2) of the act) that reasonably supports the conclusion that an exempt infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer may not provide the nutrients required by paragraph (b) or (c) of this section, or when there is an exempt infant formula that may be otherwise adulterated or misbranded and if so adulterated or misbranded presents a risk of human health. This notification shall be made, by telephone, to the Director of the appropriate FDA district office specified in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), contact the FDA Emergency Call Center at 866-300-4374. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied Nutrition (HFS-605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate FDA district office specified in part 5, subpart M of this chapter.

■ 5. Section 107.240 is amended by revising paragraph (b) to read as follows:

### § 107.240 Notification requirements.

\* \* \* \* \*

(b) *Method of notification.* The notification made pursuant to § 107.240(a) shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office listed in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), contact the FDA Emergency Call Center at 866-300-4374. The manufacturer shall send written confirmation of the notification to the Center for Food Safety and Applied Nutrition (HFS-605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate Food and Drug

Administration district office listed in part 5, subpart M of this chapter.

\* \* \* \* \*

## PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

■ 6. The authority citation for 21 CFR part 312 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

■ 7. Section 312.310 is amended by revising paragraph (d)(1) to read as follows:

### § 312.310 Individual patients, including for emergency use.

\* \* \* \* \*

(d) \* \* \*

(1) Emergency expanded access use may be requested by telephone, facsimile, or other means of electronic communications. For investigational biological drug products regulated by the Center for Biologics Evaluation and Research, the request should be directed to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 301-827-1800 or 1-800-835-4709, e-mail: [ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov). For all other investigational drugs, the request for authorization should be directed to the Division of Drug Information, Center for Drug Evaluation and Research, 301-796-3400, e-mail: [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov). After normal working hours (8 a.m. to 4:30 p.m.), the request should be directed to the FDA Emergency Call Center, 866-300-4374, e-mail: [emergency.operations@fda.hhs.gov](mailto:emergency.operations@fda.hhs.gov).

\* \* \* \* \*

## PART 803—MEDICAL DEVICE REPORTING

■ 8. The authority citation for 21 CFR part 803 continues to read as follows:

**Authority:** 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

■ 9. Section 803.12 is amended by revising paragraph (c) to read as follows:

### § 803.12 Where and how do I submit reports and additional information?

\* \* \* \* \*

(c) If an entity is confronted with a public health emergency, this can be brought to FDA's attention by contacting the FDA Office of Emergency Operations, Office of Crisis Management, Office of the Commissioner, at 866-300-4374, followed by the submission of an e-mail to [emergency.operations@fda.hhs.gov](mailto:emergency.operations@fda.hhs.gov) or a fax report to 301-847-8544.

\* \* \* \* \*

Dated: June 4, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

[TD 9485]

RIN 1545-BF28

### Contributed Property

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations under section 704(c) of the Internal Revenue Code (Code) providing that the section 704(c) anti-abuse rule takes into account the tax liabilities of both the partners in a partnership and certain direct and indirect owners of such partners. These final regulations further provide that a section 704(c) allocation method cannot be used to achieve tax results inconsistent with the intent of subchapter K of the Code. The final regulations affect partnerships and their partners.

**DATES:** *Effective Date:* These final regulations are effective June 9, 2010.

*Applicability Date:* These final regulations are applicable for taxable years beginning after June 9, 2010.

**FOR FURTHER INFORMATION CONTACT:** Bryan A. Rimmke at (202) 622-3050 (not a toll-free number).

### SUPPLEMENTARY INFORMATION:

#### Background

This document contains amendments to 26 CFR part 1 under section 704 of the Internal Revenue Code (Code). On May 19, 2008, a notice of proposed rulemaking (REG-100798-06, 2008-23 IRB 1135) was published in the **Federal Register** (73 FR 28765) in response to the Joint Committee on Taxation's recommendation that the partnership rules be strengthened to ensure that the allocation rules in the regulations under section 704(c) are not used to generate unwarranted benefits. *See The Report of Investigation of Enron Corporation and Related Entities Regarding Federal Tax and Compensation Issues, and Policy Recommendations*, (JCS-3-03) February 2003 at pg. 220. Because no requests to speak were submitted by August 18, 2008, no public hearing was held. Written comments, however, were