organization has yet to implement a hedge for marginal losses. Accordingly, we decline to order hedging of marginal losses at this time. Nevertheless, we recognize that a marginal loss hedge could provide benefits to certain market participants. The Commission supports development of a marginal loss hedging product if its design progresses beyond the theoretical level and it can be developed cost-effectively.

47. The Commission also denies SMUD's request to exempt long-term firm transmission customers from marginal losses and charge them actual or estimated system average losses. This raises a market design issue that has implications beyond the design of long-term firm transmission rights and is more appropriately resolved by each transmission organization on a case-by-case basis. Moreover, since we find that EPAct 2005 does not address marginal losses, this request is beyond the scope of this rulemaking proceeding.

By the Commission.

Kimberly D. Bose,

Secretary.

[FR Doc. E9–6698 Filed 3–25–09; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 26, 201, 203, 206, 310, 312, 314, 320, and 600

[Docket No. FDA–2009–N–0133]

Change of Addresses and Names; 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 a change of address for the Center for Drug Evaluation and Research's (CDER's) Central Document Room in Beltsville, MD; the relocation of certain CDER offices to the White Oak campus in Silver Spring, MD; and changes of the names of certain CDER organizational units. This action is editorial in nature and is intended to ensure the accuracy and clarity of the agency's regulations.

DATES: This rule is effective March 26, 2009.

FOR FURTHER INFORMATION CONTACT: Wendy Aaronson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1128, Silver Spring, MD 20993–0002, 301–796–0410.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in parts 1, 26, 201, 203, 206, 310, 312, 314, 320, and 600 (21 CFR parts 1, 26, 201, 203, 206, 310, 312, 314, 320, and 600) to reflect the following changes: (1) Names of certain CDER organizational units; (2) a change of address for CDER's Central Document Room in Beltsville, MD; and (3) the relocation of certain CDER offices to the White Oak campus in Silver Spring, MD. The addresses are locations to which applicants must submit information related to marketing applications or products regulated by CDER or from which the public can request information. Where appropriate, Internet addresses for obtaining information and forms are added and outdated addresses are removed.

The technical amendments made by this document are largely related to paper submissions; however, FDA is committed to adapting its business practices to evolving technology, including using the significant advancements in Web-based, electronic systems. We anticipate that, in future rulemakings, Web-based filing of most submissions will eventually be required. We anticipate that when a change to an electronic submission system is implemented, we will provide guidance to address any technical questions related to such submissions.

The technical amendments, reflected in the regulatory text of this final rule, are as follows:

- In § 1.101(d)(2)(ii), the address to submit notifications for products regulated by CDER exported under section 802 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 382) is changed to the White Oak campus.
- In Appendix E to subpart A of part 26, the contact information for CDER's Office of Compliance is updated to the White Oak campus.
- In § 201.58, the address to submit requests for waivers of labeling requirements is updated to the Beltsville Central Document Room.
- In § 203.12, the CDER address for notification of an appeal from an adverse decision regarding reimportation of an insulin-containing or prescription drug by a district office is changed to the White Oak campus.
- In § 203.37(e), the address to submit information regarding falsification of drug sample records or loss or theft of samples for prescription drugs and biological products regulated by CDER is changed to the White Oak campus.
- In § 203.70(b)(1), the address to apply for a reward for providing information leading to a criminal proceeding or conviction related to the sale, purchase, or trade of a drug sample is changed to the White Oak campus.
- In § 206.7(b)(1)(i), the address to request exemptions from imprinting requirements for solid oral dosage form drugs is updated to the Beltsville Central Document Room.
- In § 310.6(e), the address for interested parties to submit the names of drug products, and of their manufacturers or distributors, that should be subject to the same purchasing and regulatory policies as those reviewed by the Drug Efficacy Study Group is changed to the White Oak campus.
- In §§ 310.305(c) and 314.98(b), the address to submit postmarketing safety reports is updated to the Beltsville Central Document Room. (Note that applicants and any person other than the applicant whose name appears on the label of an approved drug product as a manufacturer, packer, or distributor may also elect to submit postmarketing safety reports in electronic format.)
- In §§ 310.305(d)(4) and 314.80(f)(4), the address to obtain reporting forms is updated to reflect Internet availability.
- In §§ 310.501(e) and 310.515(d), the name and address to request labeling guidance for estrogen drug products are updated to the Division of Reproductive and Urologic Products and the White Oak campus.
- In § 312.140(b), mailing instructions are updated to ensure submissions are addressed properly.
- In §§ 312.145(b) and 314.445(b), the CDER unit from which to request a list of CDER guidances is updated to the Division of Drug Information. The address is updated to the White Oak campus, and an Internet address is added to reflect the availability of the list on the Internet.
- In § 314.80(d)(2) and (f)(3)(ii), the CDER unit to contact regarding alternative reporting formats is updated to the Office of Surveillance and Epidemiology.
- In § 314.81(b)(3)(i), the address to obtain Form FDA–2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) is updated to reflect Internet availability.
- In § 314.200(a)(3), the address to request opinions of the applicability of a notice of opportunity for a hearing published in the **Federal Register** to a specific product that may be identical, related, or similar to a product listed in the notice is changed to the White Oak campus.
- In § 314.440(a), an outdated address to submit applications, abbreviated applications, and related

correspondence is removed and in § 314.440(a)(1), mailing instructions are updated to ensure submissions are addressed properly and the address to obtain folders for binding applications is updated to reflect information available at an Internet address.

• In § 320.30(c)(1), the name and address to submit general inquiries related to bioavailability requirements and methodology are updated to the Office of Clinical Pharmacology and the White Oak campus.

• In § 600.2(b)(1), the address for submitting biological product deviation reports for biological products regulated by CDER is changed to the White Oak campus.

• In § 600.2(b)(3), the address for submitting advertising and promotional labeling supplements required under § 600.12(f) is updated to the Beltsville Central Document Room.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to update names and addresses of CDER organizational units.

List of Subjects

21 CFR Part 1

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

21 CFR Part 26

Animal drugs, Biologics, Drugs, Exports, Imports.

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 203

Labeling, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

21 CFR Part 206

Drugs.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 312

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

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 320

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 600

Biologics, 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 parts 1, 26, 201, 203, 206, 310, 312, 314, 320, and 600 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR 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, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

§ 1.101 [Amended]

■ 2. Section 1.101 is amended in paragraph (d)(2)(ii) by removing ''(HFD–310)''; and by removing ''5600 Fishers Lane, Rockville, MD 20857'' and adding in its place ''10903 New Hampshire Ave., Silver Spring, MD 20993–0002''.

PART 26—MUTUAL RECOGNITION OF PHARMACEUTICAL GOOD MANUFACTURING PRACTICE REPORTS, MEDICAL DEVICE QUALITY SYSTEM AUDIT REPORTS, AND CERTAIN MEDICAL DEVICE PRODUCT EVALUATION REPORTS: UNITED STATES AND THE EUROPEAN COMMUNITY

■ 3. The authority citation for 21 CFR part 26 continues to read as follows:

Authority: 5 U.S.C. 552; 15 U.S.C. 1453, 1454, 1455; 18 U.S.C. 1905; 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, 360l, 360m, 371, 374, 381, 382, 383, 393; 42 U.S.C. 216, 241, 242l, 262, 264, 265.

■ 4. Appendix E to subpart A of part 26 is amended under the heading ''B. Forthe United States:'' in the entry for ''Human Drugs'' by removing ''(HFD–300), 5600 Fishers Lane, Rockville, MD 20857, phone: 301–827–8910, fax: 301–827–8901'' and by adding in its place ''10903 New Hampshire Ave., Silver Spring, MD 20993–0002, phone: 301–796–3100, fax: 301–847–8747''.

PART 201—LABELING

■ 5. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

§ 201.58 [Amended]

■ 6. Section 201.58 is amended in the second sentence by removing ''5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''Central Document Room, 5901–B Ammendale Rd., Beltsville, MD 20705–1266''.

PART 203—PRESCRIPTION DRUG MARKETING

■ 7. The authority citation for 21 CFR part 203 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.

§ 203.12 [Amended]

■ 8. Section 203.12 is amended by removing ''(HFD–300)'' both times it appears; and by removing ''5600 Fishers Lane, Rockville, MD 20857'' both times it appears and adding in its place ''10903 New Hampshire Ave., Silver Spring, MD 20993–0002''.

§ 203.37 [Amended]

■ 9. Section 203.37 is amended in the first sentence of paragraph (e) by removing ''(HFD–330)''; and by removing ''5600 Fishers Lane, Rockville, MD 20857'' and adding in its place ''10903 New Hampshire Ave., Silver Spring, MD 20993–0002''.

§ 203.70 [Amended]

■ 10. Section 203.70 is amended in paragraph (b)(1) by removing ''(HFD–300)''; and by removing ''5600 Fishers Lane, Rockville, MD 20857'' and adding in its place ''10903 New Hampshire Ave., Silver Spring, MD 20993–0002''.

PART 206—IMPRINTING OF SOLID ORAL DOSAGE FORM DRUG PRODUCTS FOR HUMAN USE

■ 11. The authority citation for 21 CFR part 206 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 355, 371; 42 U.S.C. 262.

§ 206.7 [Amended]

■ 12. Section 206.7 is amended in paragraph (b)(1)(i) by removing ''5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''5901–B Ammendale Rd., Beltsville, MD 20705–1266''.

PART 310—NEW DRUGS

■ 13. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374,

375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

§ 310.6 [Amended]

■ 14. Section 310.6 is amended in the first sentence of paragraph (e) by removing ''HFD–300, 5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''10903 New Hampshire Ave., Silver Spring, MD 20993–0002''.

■ 15. Section 310.305 is amended in paragraph (c) by removing ''Division of Pharmacovigilance and Epidemiology (HFD–730)'' and by adding in its place ''Central Document Room''; by removing ''5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''5901–B Ammendale Rd., Beltsville, MD 20705–1266''; and by revising paragraph (d)(4) to read as follows:

§ 310.305 Records and reports concerning adverse drug experiences on marketed prescription drugs for human use without approved new drug applications.

* * * * *

(d) * * *

(4) FDA Form 3500A and instructions for completing the form are available on the Internet at *http://www.fda.gov/medwatch/index.html*.

* * * * *

§ 310.501 [Amended]

■ 16. Section 310.501 is amended in paragraph (e) by removing ''Metabolism and Endocrine Drug Products (HFD–510)'' and by adding in its place ''Reproductive and Urologic Products'' and by removing ''5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''10903 New Hampshire Ave., Silver Spring, MD 20993–0002''.

§ 310.515 [Amended]

■ 17. Section 310.515 is amended in the second sentence of paragraph (d) by removing ''Metabolism and Endocrine Drug Products (HFD–510)'' and by adding in its place ''Reproductive and Urologic Products'' and by removing ''5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''10903 New Hampshire Ave., Silver Spring, MD 20993–0002''.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

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

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 371, 381, 383, 393; 42 U.S.C. 262.

§ 312.140 [Amended]

■ 19. Section 312.140 is amended in the second sentence of paragraph (b) by removing ''directed to the appropriate Center and division'' and by adding in its place ''sent to the appropriate center at the address indicated in this section and marked to the attention of the responsible division''.

§ 312.145 [Amended]

■ 20. Section 312.145 is amended in the third sentence of paragraph (b) by removing ''Division of Communications Management, Drug Information Branch (HFD–210)'' and by adding in its place ''Division of Drug Information'' and by removing ''5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''10903 New Hampshire Ave., Silver Spring, MD 20993–0002''.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 21. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

■ 22. Section 314.80 is amended as follows:

■ a. In the second sentence of paragraph (d)(2), by removing ''Division of Pharmacovigilance and Epidemiology'' and by adding in its place ''Office of Surveillance and Epidemiology''; and

■ b. By revising paragraphs (f)(3)(ii) and (f)(4) to read as follows:

The revisions read as follows:

§ 314.80 Postmarketing reporting of adverse drug experiences.

* * * * *

(f) * * *

(3) * * * (ii) The format is agreed to in advance by the Office of Surveillance and Epidemiology.

(4) FDA Form 3500A and instructions for completing the form are available on the Internet at *http://www.fda.gov/medwatch/index.html*.

* * * * *

■ 23. Section 314.81 is amended by revising the last sentence of paragraph (b)(3)(i) to read as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(3) * * *

(i) * * *Form FDA–2253 is available on the Internet at *http://www.fda.gov/opacom/morechoices/fdaforms/cder.html*.

* * * * *

§ 314.98 [Amended]

■ 24. Section 314.98 is amended in paragraph (b) by removing ''Division of Epidemiology and Surveillance (HFD–730)'' and by adding in its place ''Central Document Room'' and by removing ''5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''5901–B Ammendale Rd., Beltsville, MD 20705–1266''.

§ 314.200 [Amended]

■ 25. Section 314.200 is amended in the second sentence of paragraph (a)(3) by removing ''(HFD–310)''; and by removing ''5600 Fishers Lane, Rockville, MD 20857'' and adding in its place ''10903 New Hampshire Ave., Silver Spring, MD 20993–0002''.

■ 26. Section 314.440 is amended by revising paragraph (a) introductory text, and paragraph (a)(1) to read as follows:

§ 314.440 Addresses for applications and abbreviated applications.

(a) Applicants shall send applications, abbreviated applications, and other correspondence relating to matters covered by this part, except for products listed in paragraph (b) of this section, to the appropriate office identified below:

(1) Except as provided in paragraph (a)(4) of this section, an application under § 314.50 or § 314.54 submitted for filing should be directed to the Central Document Room, 5901–B Ammendale Rd., Beltsville, MD 20705–1266. Applicants may obtain information about folders for binding applications on the Internet at *http://www.fda.gov/cder/ddms/binders.htm*. After FDA has filed the application, the agency will inform the applicant which division is responsible for the application. Amendments, supplements, resubmissions, requests for waivers, and other correspondence about an application that has been filed should be addressed to 5901–B Ammendale Rd., Beltsville, MD 20705–1266, to the attention of the appropriate division.

* * * * *

§ 314.445 [Amended]

■ 27. Section 314.445 is amended in the third sentence of paragraph (b) by removing ''Division of Communications Management, Drug Information Branch (HFD–210)'' and by adding in its place ''Division of Drug Information'' and by removing ''5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''10903 New Hampshire Ave., Silver Spring, MD 20993–0002''.

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

■ 28. The authority citation for 21 CFR part 320 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 371.

§ 320.30 [Amended]

■ 29. Section 320.30 is amended in paragraph (c)(1) by removing ''and Biopharmaceutics (HFD–850), 5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place '', 10903 New Hampshire Ave., Silver Spring, MD 20993–0002''.

PART 600—BIOLOGICAL PRODUCTS: GENERAL

■ 30. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25.

§ 600.2 [Amended]

■ 31. Section 600.2 is amended as follows:

a. In paragraph (b)(1) by removing ''(HFD–330)''; and by removing ''5600 Fishers Lane, Rockville, MD 20857'' and adding in its place ''10903 New Hampshire Ave., Silver Spring, MD 20993–0002''; and

b. In paragraph (b)(3) by removing ''(HFD–42)''; and by removing ''5600 Fishers Lane, rm. 8B45, Rockville, MD 20857'' and adding in its place ''5901–B Ammendale Rd., Beltsville, MD 20705–1266''.

Dated: March 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–6795 Filed 3–25–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds

CFR Correction

In title 21 of the Code of Federal Regulations, part 558, revised as of April 1, 2008, on page 410, in § 558.58 (e)(1)(iii), the entry for Bambermycins 1 to 3, in the column under ''Limitations'' remove ''057926'' and in its place add ''016592''; in the column under ''Sponsors'', add ''016592''.

[FR Doc. E9–6810 Filed 3–25–09; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 101

[Docket Nos. TSA–2006–24191; USCG–2006–24196]

RIN 1652–AA41

Transportation Worker Identification Credential (TWIC) Implementation in the Maritime Sector; Hazardous Materials Endorsement for a Commercial Driver's License

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Department of Homeland Security (DHS) through the United States Coast Guard (Coast Guard) issues this final rule to amend one provision of its previously issued final rule. Specifically, the Coast Guard is amending its definition of secure area to take into account facilities in American Samoa, whose workers are not required to be authorized to work in the United States under U.S. immigration law when working in American Samoa.

DATES: This final rule is effective March 26, 2009.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of dockets TSA–2006–24191 and USCG–2006–24196, and are available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet by going to *http://www.regulations.gov*, selecting the Advanced Docket Search option on the right side of the screen, inserting TSA–2006–24191 or USCG–2006–24196 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call LCDR Jonathan Maiorine, Coast Guard; telephone 1–877–687–2243. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

I. Regulatory History

On May 22, 2006, the Department of Homeland Security (DHS), through the United States Coast Guard (Coast Guard) and the Transportation Security Administration (TSA), published a joint notice of proposed rulemaking entitled ''Transportation Worker Identification Credential (TWIC) Implementation in the Maritime Sector; Hazardous Materials Endorsement for a Commercial Driver's License'' in the **Federal Register** (71 FR 29396). This was followed by a 45-day comment period and four public meetings. The Coast Guard and TSA issued a joint final rule, under the same title, on January 25, 2007 (72 FR 3492) (hereinafter referred to as the original TWIC final rule). The preamble to that final rule contains a discussion of the provisions found in the original TWIC final rule, which became effective on March 26, 2007.

On September 28, 2007, the Coast Guard and TSA issued a joint final rule (72 FR 55043) that, among other things, revised the definition for ''secure area'' to account for facilities in the Commonwealth of the Northern Mariana Islands (the CNMI), as non-citizen workers at those facilities are not required to have authorization to work in the United States under U.S. immigration law before being allowed to work.

On May 7, 2008, the Coast Guard and TSA issued a joint final rule to realign the compliance date for implementation of the original TWIC final rule (*see* 73 FR 25562). The date by which mariners need to obtain a TWIC, and by which owners and operators of vessels and outer continental shelf facilities must implement access control procedures using TWIC, is April 15, 2009. Owners and operators of facilities that must comply with 33 CFR part 105 are subject to earlier, rolling compliance dates, as set forth in 33 CFR 105.115(e). The Coast Guard announced these rolling compliance dates via notices published in the **Federal Register**. The final compliance date for all COTP Zones is not later than April 15, 2009.

On September 30, 2008, the Coast Guard announced the compliance date for COTP Zone Honolulu would be February 12, 2009 (73 FR 56730). On February 12, 2009, the Coast Guard announced the extension of that compliance date, for the territory of American Samoa only, to April 14, 2009, due to the fact that a large percentage of the maritime workforce is not native to the island, and does not need to be authorized to work in the United States under U.S. immigration law before being allowed to work in American Samoa. In that notice, the Coast Guard stated that the extension was being granted in order to allow time