provide information at the time of entry of the merchandise on the entry summary form, CBP Form 7501, as to whether the value of the imported merchandise was determined on the basis of the price paid by the buyer in the ''first or earlier sale.'' The likely respondents are business organizations including importers and brokers. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB. This collection of information falls under the previously approved collection 1651–0022 for the Entry Summary, CBP Form 7501.

Signing Authority

This document is being issued in accordance with § 0.1(a)(1) of title 19 of the Code of Federal Regulations (19 CFR 0.1(a)(1)) pertaining to the authority of the Secretary of the Treasury (or his/her delegate) to approve regulations related to certain customs revenue functions.

List of Subjects in 19 CFR Part 141

Customs duties and inspection, Entry of merchandise, Reporting and recordkeeping requirements.

Amendments to the Regulations

■ For the reasons stated above, part 141 of title 19 of the Code of Federal Regulations (19 CFR part 141) is amended as set forth below.

PART 141—ENTRY OF MERCHANDISE

■ 1. The general authority citation for part 141 continues to read, and the specific authority for § 141.16 is added, to read as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1624.

* * * * *

Section 141.61 also issued under sec. 15422(a), Pub. L. 110–234, 122 Stat. 1547 (19 U.S.C. 1484 note) and 19 U.S.C. 1401a.

* * * * *

■ 2. Section 141.61 is amended by adding a new paragraph (g) to read as follows:

§ 141.61 Completion of entry and entry summary documentation.

* * * * *

(g) *Declaration of value.* Pursuant to section 15422(a) of the Food, Conservation, and Energy Act of 2008 (Pub. L. 110–234), for all goods entered for consumption or withdrawn from warehouse for consumption from August 20, 2008 through August 19, 2009, an importer of merchandise must enter an ''F'' next to the declared value on CBP Form 7501, or the electronic filing equivalent, when the declared transaction value of the imported merchandise is determined on the basis of the price paid by the buyer in a sale occurring earlier than the last sale prior to the introduction of the merchandise into the United States.

W. Ralph Basham,

Commissioner, U.S. Customs and Border Protection.

Approved: August 20, 2008.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. E8–19640 Filed 8–20–08; 4:15 pm]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 610, 640, 812, 814, 822, and 860

[Docket No. FDA–2008–N–0423]

FDA Regulations; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a regulatory hearing process regulation to correct an inaccurate citation, and regulations pertaining to biological products to correct two typographical errors. FDA is also amending certain medical device regulations to include references to and mailing address information for the Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH). This action is being taken to ensure the accuracy of FDA's regulations.

DATES: This rule is effective August 25, 2008.

FOR FURTHER INFORMATION CONTACT: Denise Sánchez, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is amending 21 CFR 16.1 to correct an inaccurate citation and is amending 21 CFR 610.51 and 21 CFR 640.53 to correct typographical errors.

FDA is also amending its medical device regulations in 21 CFR 812, 814, and 860 to include references to and mailing addresses for CBER and CDER, and 21 CFR 822.8 to correct an inadvertent omission of the mailing address for CDRH. Submissions regarding a medical device must be sent to the address of the appropriate center that has regulatory responsibility for the medical device. Therefore, FDA is updating these regulations to include address information for all appropriate centers.

Publication of this document constitutes final action under the Administrative Procedures 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 correct an inaccurate citation and typographical errors, and to update mailing addresses and other information, and is nonsubstantive.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 640

Blood, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 822

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 860

Administrative practice and procedure, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 16, 610, 640, 812, 814, 822, and 860 are amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

§ 16.1 [Amended]

■ 2. Section 16.1 is amended in paragraph (b)(2), by removing ''§ 1270.15(e)'' and adding in its place ''§ 1270.43(e)''.

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 3. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 610.53 [Amended]

■ 4. Section 610.53 is amended in paragraph (c) in the table, under column A, by removing the words ''Cryoprecipitated AFH'' and adding in their place ''Cryoprecipitated AHF.''

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

■ 5. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 640.51 [Amended]

■ 6. Section 640.51 is amended in paragraph (b) by removing the word ''Plasmaphersis'' and adding in its place ''Plasmapheresis.''

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

■ 7. The authority citation for 21 CFR part 812 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

■ 8. Section 812.20 is amended by revising paragraph (d) to read as follows:

§ 812.20 Application.

* * * * *

(d) *Information previously submitted.* Information previously submitted to the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, or the Center for Drug Evaluation and Research, as applicable, in accordance with this chapter ordinarily need not be resubmitted, but may be incorporated by reference.

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 9. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 10. Section 814.42 is amended by revising the fourth sentence of paragraph (d)(2) to read as follows:

§ 814.42 Filing a PMA.

* * * * *

(d) * * *

(2) * * * If FDA does not reverse its decision not to file the PMA, the applicant may request reconsideration of the decision from the Director of the Center for Devices and Radiological Health, the Director of the Center for Biologics Evaluation and Research, or the Director of the Center for Drug Evaluation and Research, as applicable. * * *

* * * * * *

■ 11. Section 814.100 is amended by revising paragraph (c)(2) to read as follows:

§ 814.100 Purpose and scope.

* * * * *

(c) * * *

(2) Submitting an HDE to the Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), or the Center for Drug Evaluation and Research (CDER), as applicable.

* * * * *

■ 12. Section 814.104 is amended by revising paragraph (d) to read as follows:

§ 814.104 Original applications.

* * * * *

(d) *Address for submissions and correspondence.* Copies of all original HDEs amendments and supplements, as well as any correspondence relating to an HDE, must be sent or delivered to the following:

(1) For devices regulated by the Center for Devices and Radiological Health, send this information to the Document Mail Center (HFZ–401), Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

(2) For devices regulated by the Center for Biologics Evaluation and Research, send this information to the Document Control Center (HFM–99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

(3) For devices regulated by the Center for Drug Evaluation and Research, send this information to the Central Document Control Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266.

PART 822—POSTMARKET SURVEILLANCE

■ 13. The authority citation for 21 CFR part 822 continues to read as follows:

Authority: 21 U.S.C. 331, 352, 360i, 360l, 371, 374.

■ 14. Section 822.8 is amended by adding a sentence after the first sentence to read as follows:

§ 822.8 When, where, and how must I submit my postmarket surveillance plan?

* * * For devices regulated by the Center for Devices and Radiological Health, send three copies of your submission to the Postmarket Surveillance Document Center (HFZ–541), Epidemiology Branch, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. * * *

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

■ 15. The authority citation for 21 CFR part 860 continues to read as follows:

Authority: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

■ 16. Section 860.7 is amended by revising paragraph (g)(4) to read as follows:

§ 860.7 Determination of safety and effectiveness.

* * * * *

(g) * * *

(4) Required information that has been submitted previously to the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, or the Center for Drug Evaluation and Research, as applicable, need not be resubmitted, but may be incorporated by reference.

■ 17. Section 860.123 is amended by revising paragraph (b)(1) to read as follows:

§ 860.123 Reclassification petition: Content and form.

* * * * *

(b) * * *

(1) For devices regulated by the Center for Devices and Radiological Health, addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Regulations Staff

(HFZ–215), 1350 Piccard Dr., Rockville, MD 20857; for devices regulated by the Center for Biologics Evaluation and Research, addressed to the Document Control Center (HFM–99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; for devices regulated by the Center for Drug Evaluation and Research, addressed to the Central Document Control Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266, as applicable.

* * * * *

Dated: August 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19654 Filed 8–22–08; 8:45 am]

BILLING CODE 4160–01–S

PEACE CORPS

22 CFR Part 304

RIN 0420–AA23

Claims Against the Government Under the Federal Tort Claims Act

AGENCY: Peace Corps.

ACTION: Final rule.

SUMMARY: The Peace Corps is revising its regulation concerning claims filed under the Federal Tort Claims Act, to make the regulation internally consistent with another provision stating that the Chief Financial Officer has authority to approve claims for amounts under $5000.

DATES: The final rule is effective September 24, 2008.

FOR FURTHER INFORMATION CONTACT: Nancy G. Miller, Associate General Counsel, Office of the General Counsel, 202–692–2150.

SUPPLEMENTARY INFORMATION: The Peace Corps published a proposed rule on July 9, 2008, for public review and comment. See 73 FR 39270, (July 9, 2008). The Peace Corps received no public comments and the Agency has made no further revisions. Therefore, this rule is final and will be effective on the date stated above.

On March 16, 2007, Peace Corps revised 22 CFR 304.7 to provide that the Chief Financial Officer ''has the authority to adjust, determine, compromise, and settle claims for less than $5,000.'' This final rule will rectify an omission in sec. 304.10 which did not refer to the Chief Financial Officer's authority for deciding claims worth less than $5,000.

This rule amends section 304.10(b) to provide that the Chief Financial Officer will make final determinations for claims worth less than $5,000.

Executive Order 12866

This regulation has been determined to be non-significant within the meaning of Executive Order 12866.

Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b))

This regulatory action will not have a significant adverse impact on a substantial number of small entities.

Unfunded Mandates Act of 1995 (Sec. 202, Pub. L. 104–4)

This regulatory action does not contain a Federal mandate that will result in the expenditure by state, local, and tribal governments, in aggregate, or by the private sector of $100 million or more in any one year.

Paperwork Reduction Act of 1995 (44 U.S.C., Chapter 35)

This regulatory action will not impose any additional reporting or recordkeeping requirements under the Paperwork Reduction Act.

Federalism (Executive Order 13132)

This regulatory action does not have Federalism implications, as set forth in Executive Order 13132. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

List of Subjects in 22 CFR Part 304

Claims.

■ Accordingly, Peace Corps amends 22 CFR part 304 as follows:

PART 304—CLAIMS AGAINST THE GOVERNMENT UNDER THE FEDERAL TORT CLAIMS ACT

■ 1. The authority citation for part 304 continues to read as follows:

Authority: 28 U.S.C. 2672; 22 U.S.C. 2503(b); E.O. 12137, as amended.

■ 2. Amend § 304.10 by revising paragraph (b) to read as follows:

§ 304.10 Review of claim.

* * * * *

(b) After legal review and recommendation by the General Counsel, the Director of the Peace Corps will make a written determination on the claim, unless the claim is worth less than $5,000, in which case the Chief Financial Officer will make the written determination.

Dated: August 18, 2008.

Tyler Posey,

General Counsel.

[FR Doc. E8–19642 Filed 8–22–08; 8:45 am]

BILLING CODE 6015–01–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 203, 250, 251, 256, 280, 281, and 290

[Docket ID: MMS–2007–OMM–0065]

RIN 1010–AD43

Electronic Payment of Fees for Outer Continental Shelf Activities

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: This final rule requires that all lessees, operators, permittees, and right-of-way holders pay all fees for processing plans, applications, and permits electronically. This rule will aid industry in payment processing and reduce payment processing errors. This rule will improve MMS processing efficiency and facilitate the correction of industry payment errors. The MMS will not accept checks, money orders, or cashier's checks for payment of fees after the effective date of this final rule. The final rule also adjusts certain cost recovery fees for inflation.

DATES: *Effective Date:* This rule becomes effective on September 24, 2008.

FOR FURTHER INFORMATION CONTACT: Kirk Malstrom, Office of Offshore Regulatory Programs, Regulations and Standards Branch, (703) 787–1751.

SUPPLEMENTARY INFORMATION:

Background

The MMS published a proposed rule on December 21, 2007 (72 FR 72648), that would require all lessees, operators, pipeline right-of-way (ROW) holders, and permittees to submit payments for cost recovery service fees electronically. The comment period for the proposed rule closed February 19, 2008, and Chevron submitted the one and only comment on the proposed rule. The commenter supports the concept of submitting fees electronically through *Pay.gov.* The commenter stated concerns about only using *Pay.gov* and provided rule language to allow alternatives for a different payment portal if so needed. The MMS believes *Pay.gov* to be the best option for paying