

In compliance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding this information collection to the Office of Information and Regulatory Affairs, OMB (see ADDRESSES).

## XI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that 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. Accordingly, the agency has concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## XII. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Minutes, Pharmaceutical Sciences Advisory Committee, November 16, 2000.
2. U. S. Department of Labor, Bureau of Labor Statistics, Table 20: Private Industry, Health Services, Employer Costs per Hour Worked for Employee Compensation, Professional Specialty and Technical Occupations, available online at [www.bls.gov/ncs/ect/sp/ecechist.pdf](http://www.bls.gov/ncs/ect/sp/ecechist.pdf).
3. U. S. Small Business Administration, Office of Size Standards, Table of Size Standards, available online at [www.sba.gov/size/indextableofsize.html](http://www.sba.gov/size/indextableofsize.html).
4. Balaji, K., "Generics, The Opportunity Beckons," as reported by Frost and Sullivan ([www.frost.com](http://www.frost.com)), 4 July 2001.
5. Humphreys, A., "Generics: Gaining Momentum, Special Report," *Med Ad News*, vol. 19, p. 42, October 2000.

## List of Subjects

### 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.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner

of Food and Drugs, it is proposed that 21 CFR parts 314 and 320 be amended as follows:

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

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

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

2. Section 314.94 is amended by revising paragraph (a)(7)(i) to read as follows:

### § 314.94 Content and format of an abbreviated application.

(a) \* \* \*

(7) *Bioequivalence.* (i) Information that shows that the drug product is bioequivalent to the reference listed drug upon which the applicant relies. A complete study report must be submitted for the bioequivalence study upon which the applicant relies for approval. For all other bioequivalence studies conducted on the same drug product formulation, the applicant must submit either a complete or summary report. If a summary report of a bioequivalence study is submitted and FDA determines that there may be bioequivalence issues or concerns with the product, FDA may require that the applicant submit a complete report of the bioequivalence study to FDA; or

3. Section 314.96 is amended by adding four sentences at the end of paragraph (a)(1) to read as follows:

### § 314.96 Amendments to an unapproved abbreviated application.

(a) \* \* \*

(1) \* \* \* Amendments containing bioequivalence studies must contain reports of all bioequivalence studies conducted by the applicant on the same drug product formulation, unless the information has previously been submitted to FDA in the abbreviated new drug application. A complete study report must be submitted for any bioequivalence study upon which the applicant relies for approval. For all other bioequivalence studies conducted on the same drug product formulation, the applicant must submit either a complete or summary report. If a summary report of a bioequivalence study is submitted and FDA determines that there may be bioequivalence issues or concerns with the product, FDA may require that the applicant submit a complete report of the bioequivalence study to FDA.

\* \* \* \* \*

## PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

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

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

5. Section 320.21 is amended by revising paragraph (b)(1) to read as follows:

### § 320.21 Requirements for submission of in vivo bioavailability and bioequivalence data.

\* \* \* \* \*

(b) \* \* \*

(1) Evidence demonstrating that the drug product that is the subject of the abbreviated new drug application is bioequivalent to the reference listed drug (defined in § 314.3(b)). A complete study report must be submitted for the bioequivalence study upon which the applicant relies for approval. For all other bioequivalence studies conducted on the same drug product formulation, the applicant must submit either a complete or summary report. If a summary report of a bioequivalence study is submitted and FDA determines that there may be bioequivalence issues or concerns with the product, FDA may require that the applicant submit a complete report of the bioequivalence study to FDA; or

\* \* \* \* \*

Dated: October 7, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-27187 Filed 10-28-03; 8:45 am]

BILLING CODE 4160-01-S

## POSTAL SERVICE

### 39 CFR Part 111

### Refund Procedures for Metered Postage

**AGENCY:** Postal Service.

**ACTION:** Proposed rule.

**SUMMARY:** The Postal Service proposes to revise the *Domestic Mail Manual* (DMM) to allow refunds for unused, undated metered postage. The proposed mailing standard would benefit any mailer who generates significant quantities of unused, undated metered postage and is able to meet the refund criteria. The Postal Service also proposes minor clarifications to the procedures for requesting refunds for unused, dated metered postage.

**DATES:** Submit comments on or before November 28, 2003.

**ADDRESSES:** Mail or deliver written comments to Charles Tricamo, New

York Rates and Classification Service Center, Postal Service, 1250 Broadway FL 14, New York, NY, 10095-9599. You can view and copy all written comments at the same address between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:**

Charles Tricamo, New York Rates and Classification Service Center, at 212-613-8676.

**SUPPLEMENTARY INFORMATION:** Inclusion of a date in meter indicia is optional for Standard Mail and Package Services items. Many mailers choose to omit the date to increase their production flexibility and allow them to deposit the mailing at any time, even though Postal Service mailing standards do not allow refunds for unused meter indicia lacking a date. The Postal Service grants refunds only for unused, dated meter indicia if requested within 60 days of printing the indicia. The Postal Service proposes that if the mailer can provide sufficient documentation with the refund request to support and validate the proper amount of the refund, the date the mailing was prepared, and the validity of the indicia on the mailpieces, then it could grant refunds for undated metered mail. The Postal Service proposes to apply the existing time frame restrictions for dated metered mail to undated metered mail. Additionally, the Postal Service proposes that refunds for unused, undated metered postage will only be considered when the customer submits at least 500 mailpieces from a single mailing, or, as an alternative, indicia worth at least \$500 from a single mailing, along with the required supporting documentation. When more than one meter was used to prepare the mailing, a separate PS Form 3533, *Application and Voucher for Refund of Postage, Fees, and Services*, must be submitted for each meter used to print the unused indicia submitted for refund. Mailers concerned about their inability to obtain a refund for unused, undated metered postage because they have less than the required mail volume or cannot provide the required documentation should use dated meter indicia or permit imprint for their Standard Mail and Package Services mailpieces, as permitted, in lieu of undated meter indicia.

As part of this proposed rule, the Postal Service also proposes to revise DMM P014, Refunds and Exchanges, to clarify the mailing standards for refunds of unused, dated meter indicia. Portions of P014 are reorganized to consolidate all of the information related to submitting a refund request for unused meter indicia. Also included is a

proposed clarification to specify that a contract postal unit (CPU) will handle refunds for unused meter indicia in accordance with the contract each CPU has executed with the Postal Service for the sale of metered postage.

Although exempt from the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b), (c)) regarding proposed rulemaking by 39 U.S.C. 410(a), the Postal Service invites public comments on the following proposed amendments to the *Domestic Mail Manual*, incorporated by reference in the *Code of Federal Regulations*. See CFR part 111.

**List of Subjects in 39 CFR Part 111**

Administrative practice and procedure, Postal Service.

For reasons stated in the preamble, the Postal Service proposes to amend 39 CFR part 111 as follows:

**PART 111—[AMENDED]**

1. The authority citation for 39 CFR part 111 continues to read as follows:

**Authority:** 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001, 3011, 3201, 3219, 3403-3406, 3621, 3626, 5001.

2. Revise *Domestic Mail Manual* (DMM) as set forth below:

**Domestic Mail Manual (DMM)**

\* \* \* \* \*

**P Postage and Payment Methods**

*P000 Basic Information*

*P010 General Standards*

\* \* \* \* \*

*P014 Refunds and Exchanges*

\* \* \* \* \*

**2.0 Postage and Fees Refunds**

**2.1 Refund Standards**

A refund for postage and fees may be made:

\* \* \* \* \*

[Add new item e to read as follows:]

e. Under the terms of a contract between the contract postal unit (CPU) and the USPS® for unused postage printed by the CPU.

\* \* \* \* \*

[Delete 2.5 and 2.6. Renumber current 2.7 through 2.12 as new 2.5 through 2.10, respectively.]

\* \* \* \* \*

**2.7 Applying for Refund**

[Revise text of renumbered 2.7 to read as follows:]

For refunds under 2.0, the customer must apply for a refund on PS Form 3533; submit it to the postmaster; and

provide the envelope, wrapper, or a part of it showing the names and addresses of the sender and addressee, canceled postage and postal markings, or other evidence of postage and fees paid. Refunds for metered postage are submitted under 3.0.

**2.8 Ruling on Refund Request**

[Revise text of renumbered 2.8 to read as follows:]

Refund requests are decided based on the specific type of postage or mailing:

a. Refunds under 2.0. The local postmaster grants or denies refunds under 2.0. The customer may appeal an adverse ruling through the postmaster to the rates and classification service center (RCSC) manager who issues the final agency decision.

b. Dated metered postage, except for PC Postage® systems, under 3.0. The postmaster at the licensing Post Office™ grants or denies requests for refunds for dated metered postage under 3.0. The licensee may appeal an adverse ruling within 30 days through the manager of Postage Technology Management, USPS Headquarters (see G043 for address), who issues the final agency decision. The original meter indicia must be submitted with the appeal.

c. Undated metered postage under 3.0. The manager, business mail entry (MBME) at the district Post Office overseeing the mailer's licensing Post Office, or designee, grants or denies requests for refunds for undated metered postage under 3.0. The customer may appeal a decision on undated metered postage within 30 days through the MBME, or designee, to the RCSC manager who issues the final agency decision. The original meter indicia must be submitted with the appeal.

d. PC Postage systems under 3.0. The system provider grants or denies a request for a refund for dated indicia printed by PC Postage systems under 3.0 using established USPS criteria. For dated PC Postage indicia only, the licensee may appeal an adverse ruling within 30 days through the manager of Postage Technology Management, USPS Headquarters, who issues the final agency decision. The original indicia must be submitted with the appeal.

e. Optional procedure (OP) mailings. Mailer's request for a refund must be submitted to the manager of Business Mailers Support (BMS), USPS Headquarters (see G043 for address).

\* \* \* \* \*

### 3.0 Refund Request for Postage Evidencing Systems and Metered Postage

\* \* \* \* \*

*[Revise title and text of 3.2 to read as follows:]*

#### 3.2 Unused, Dated Postage Evidencing System Indicia, Except for PC Postage Indicia

Unused, dated postage meter indicia are considered for refund only if complete, legible, and valid. PC Postage indicia refunds are processed under 3.3. All other metered postage refund requests must be submitted as follows:

a. The licensee must submit the request. The refund request must include proof that the person or entity requesting the refund is the licensee for the postage meter that printed the indicia. Acceptable proof includes a copy of the lease, rental agreement, or contract.

b. The licensee must submit the request, along with the items bearing the unused postage, to the licensing Post Office. The items must be sorted by meter used and then by postage value shown in the indicia, and must be properly faced and packaged in groups of 100 identical items when quantities allow. The request is processed by the USPS. The postmaster approves or denies the refund request.

c. The licensee must submit the refund request within 60 days of the date(s) shown in the indicia.

d. When the unused metered postage is affixed to a mailpiece, the refund request must be submitted with the entire envelope or wrapper. The unused metered postage must not be removed from the mailpiece once applied.

e. Indicia printed on labels or tapes not stuck to wrappers or envelopes must be submitted loose and must not be stapled together or attached to any paper or other medium. However, self-adhesive labels printed without a backing may be submitted on a plain sheet of paper.

f. If a part of one indicium is printed on one envelope or card and the remaining part on one or more others, they must be fastened together to show that they represent one indicium.

g. Refunds are allowable for indicia on metered reply envelopes only when it is obvious that an incorrect amount of postage was printed on them.

h. The refund request must be submitted with a properly completed PS Form 3533 (see I021). A separate PS Form 3533 must be completed for each meter for which a refund is requested. All identifying information and all sections related to the refund requested

must be completed. Charges for processing a refund request for unused, dated meter indicia are as follows:

(1) If the total face value of the indicia is \$350 or less, the amount refunded is 90% of the face value. USPS may process the refund payment locally via a no-fee postal money order.

(2) If the total face value is more than \$350, the amount refunded is reduced by a figure representing \$35 per hour, or fraction thereof, for the actual hours to process the refund, with a minimum charge of \$35. The postmaster will submit the approved PS Form 3533 to the USPS Imaging and Scanning Center for payment processing through the Accounting Service Center.

*[Renumber current 3.3 and 3.4 as new 3.5 and 3.6, respectively. Add new 3.3 and 3.4 to read as follows:]*

#### 3.3 Unused, Dated PC Postage Indicia

Unused, dated PC Postage indicia are considered for refund only if complete, legible, and valid. The refund request must be submitted as follows:

a. Only the PC Postage licensee may request the refund. The licensee must submit the request, along with the items bearing the unused postage, to the system provider. The request is processed by the provider, not the USPS.

b. The licensee must submit the refund request within 30 days of the date(s) shown in the indicia.

c. The refund request must be submitted as required by 3.2.d through 3.2.g.

d. The provider may, at its discretion, charge for processing a refund request.

#### 3.4 Undated Metered Postage

Unused, undated postage evidencing system indicia are considered for refund only if complete, legible, and valid. The refund request must be submitted as follows:

a. Only the meter licensee or the commercial entity that prepared the mailing for the licensee using the licensee's meter may request the refund. The request must include a letter signed by the meter licensee or the commercial entity that prepared the mailing for the licensee explaining why the mailpieces were not mailed.

b. The minimum quantity of unused, undated metered postage that may be submitted for refund is 500 pieces from a single mailing or, as an alternative, indicia with a total postage value of at least \$500 from a single mailing.

c. The meter licensee, or the commercial entity that prepared the mailing for the licensee using the licensee's meter, must submit the request, along with the items bearing the

unused postage and the required documentation, to the manager of business mail entry at the district Post Office overseeing the mailer's licensing Post Office, or to a designee. The manager or designee approves or denies the refund request.

d. The request must include the items bearing the unused postage, sorted by meter used and then by postage value shown in the indicia. The items must be properly faced and packaged in groups of 100 identical items, when quantities allow, and must meet the requirements of 3.2.d through 3.2.g.

e. The request must be submitted within 60 days of the date the mail was metered. Supporting documentation must be submitted to validate the date. Examples of supporting documentation include the job order from the customer, production records, the USPS qualification report, spoilage report, and reorders created report, as well as customer billing records, postage statements, and a sample mailpiece.

f. The refund request must be submitted with a properly completed PS Form 3533 (see I021). All identifying information and all sections related to the refund requested must be completed. When more than one meter was used to prepare the mailing, a separate PS Form 3533 must be completed for each.

(1) If the total face value of the indicia for a single mailing submitted for refund is \$350 or less, the amount refunded is 90% of the face value. USPS may process the refund payment locally via a no-fee postal money order.

(2) If the total face value of the indicia for a single mailing submitted for refund is more than \$350, the amount refunded is reduced by a figure representing \$35 per hour, or fraction thereof, for the actual hours to process the refund, with a minimum charge of \$35. The MBME will submit the approved PS Form 3533 to the USPS Imaging and Scanning Center for payment processing through the Accounting Service Center.

#### 3.5 Ineligible Metered Postage Items

The following metered postage items are ineligible for refunds:

\* \* \* \* \*

*[Revise text of renumbered 3.5.d to read as follows:]*

d. Indicia lacking identification of the licensing Post Office, or other required information.

\* \* \* \* \*

We will publish an appropriate amendment to 39 CFR 111 to reflect these changes if the proposal is adopted.

**Stanley F. Mires,**

*Chief Counsel, Legislative.*

[FR Doc. 03-27186 Filed 10-28-03; 8:45 am]

BILLING CODE 7710-12-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[SIP NO. MT-001-0048; FRL-7580-1]

#### Approval and Promulgation of Air Quality Implementation Plans; Montana; Maintenance of Air Pollution Control Equipment for Existing Aluminum Plants

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to disapprove a State Implementation Plan revision submitted by the State of Montana on January 16, 2003. This revision provides existing aluminum plants an exemption to meeting emission limits during scheduled maintenance. This action is being taken under section 110 of the Clean Air Act.

**DATES:** Written comments must be received on or before November 28, 2003.

**ADDRESSES:** Written comments may be submitted by mail to Richard R. Long, Director, Air and Radiation Program, Mailcode 8P-AR, Environmental Protection Agency (EPA), Region 8, 999 18th Street, Suite 300, Denver, Colorado 80202-2466. Comments may also be submitted electronically, or through hand delivery/courier. Please follow the detailed instructions described in (Part (I)(B)(1)(i) through (iii)) of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Laurie Ostrand, Air and Radiation Program, Mailcode 8P-AR, Environmental Protection Agency (EPA), Region 8, 999 18th Street, Suite 300, Denver, Colorado 80202, (303) 312-6437, [oststrand.laurie@epa.gov](mailto:oststrand.laurie@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Table of Contents**

- I. General Information
- II. Background
- III. Why EPA is Proposing to Disapprove the State of Montana's January 16, 2003 Submittal
- IV. Proposed Action
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#### *Definitions*

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA*, *we*, *us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The *MACT standard* refers to the National Emission Standards for Hazardous Air Pollutants for Primary Aluminum Reduction Plants.

(iv) The initials *SIP* mean or refer to State Implementation Plan.

(v) The words *State* or *Montana* mean the State of Montana, unless the context indicates otherwise.

#### **I. General Information**

##### *A. How Can I Get Copies of This Document and Other Related Information?*

1. The Regional Office has established an official public rulemaking file available for inspection at the Regional Office. EPA has established an official public rulemaking file for this action under MT-001-0048. The official public file consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public rulemaking file does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public rulemaking file is the collection of materials that is available for public viewing at the Air and Radiation Program, EPA Region 8, 999 18th Street, Suite 300, Denver, CO. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. You may view the public rulemaking file at the Regional Office Monday through Friday, 8 a.m. to 4 p.m., excluding federal Holidays.

2. Copies of the State submittal are also available for public inspection during normal business hours, by appointment at the State Air Agency. Copies of the State documents relevant to this action are available for public inspection at the Montana Department of Environmental Quality, Air and Waste Management Bureau, 1520 E. 6th Avenue, Helena, Montana 59620.

3. **Electronic Access.** You may access this **Federal Register** document electronically through the Regulations.gov Web site located at <http://www.regulations.gov> where you can find, review, and submit comments

on. Federal rules that have been published in the **Federal Register**, the Government's legal newspaper, and are open for comment.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at the EPA Regional Office, as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in the official public rulemaking file. The entire printed comment, including the copyrighted material, will be available at the Regional Office for public inspection.

##### *B. How and to Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate rulemaking identification number by including the text "Public comment on proposed rulemaking MT-001-0048" in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

1. **Electronically.** If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD-ROM you submit, and in any cover letter accompanying the disk or CD-ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.