

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.

3. U. S. Small Business Administration, Office of Size Standards, Table of Size Standards, available online at www.sba.gov/size/index.html.

4. Balaji, K., "Generics, The Opportunity Beckons," as reported by Frost and Sullivan (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

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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.

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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

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Dated: October 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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

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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