

excluded under Federal laws other than the Social Security Act. (See the appendix to this subpart.)

6. The authority citation for Subpart L of Part 416 reads as follows:

Authority: Secs. 1102, 1301, 1302, 1311, 1312, 1313, 1314(f), and 1351(d) of the Social Security Act, as amended; 49 Stat. 647, as amended; 86 Stat. 1465, 1466, 1468, 1470, 1473; 42 U.S.C. 1302, 1351, 1351a, 1352, 1352a, 1352b, 1352c(f), and 1353(d), unless otherwise noted.

7. Section 416.1201 is amended by revising the last sentence in paragraph (a) to read as follows:

§ 416.1201 Resources; general.

(a) Resources; defined. * * *

In addition, support and maintenance assistance not counted as income under § 416.1157 are not considered resources.

[FR Doc. 85-10941 Filed 5-23-85; 8:45 am]

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Food and Drug Administration 21 CFR Ch. I

[Docket No. 85N-0214]

The Drug Price Competition and Patent Term Restoration Act of 1984; Establishment of a Public File and Request for Comments

AGENCY: Food and Drug Administration.

ACTION: Request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket containing a public record of the comments, views, and other information submitted to the agency from interested persons concerning Title I of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and is inviting public comment on interpretation of the statute for purposes of the agency's regulation writing process.

DATE: Comments on Title I of Pub. L. 98-417 by July 8, 1985.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Marilyn L. Watson, Center for Drugs and Biologics (HFN-360), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-9640.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) was signed into law September 24, 1984. The new law consists of two titles that concern generic new drugs. Title I of the new law, which amends section 505 of the Federal Food, Drug, and Cosmetic Act, codifies FDA's authority to accept abbreviated new drug applications (ANDA's) for generic versions of drug products first approved after 1962. Prior to the enactment of Pub. L. 98-417, ANDA's were permitted under FDA regulations for generic versions of drug products first approved between 1938 and 1962. Title I also addresses filing and approval requirements for paper NDA's.

Title II of Pub. L. 98-417 amends the patent law to provide for the extension of the normal 17-year term of a product, use, or process patent of a patented product which is subject to premarketing clearance. In a future issue of the Federal Register, FDA will publish a similar notice concerning the establishment of a public file, and a request for comments, on Title II.

II. Public Record

FDA has established in the Dockets Management Branch, under Docket No. 85N-0214, a public file for all comments, views, and other information submitted to FDA concerning Title I of Pub. L. 98-417. Received comments will be incorporated into this public file and may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Public Comment

Section 105(a) of Pub. L. 98-417 requires FDA to promulgate implementing regulations. The new law is detailed and complex so that questions, identification of policy issues, and suggested interpretations of the new law by interested persons in the early stages of implementation of the law will assist FDA in developing these regulations in a timely fashion. Accordingly, FDA is inviting the submission of comments, views, or other information to assist the agency in its efforts to develop regulations implementing Title I of Pub. L. 98-417.

Interested persons may submit written comments on Title I of Pub. L. 98-417 to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. All comments are to be identified with the docket number found in brackets in the heading of this document. To assure consideration of comments by FDA in developing the proposed regulations, the comments on Pub. L. 98-417 should be submitted on or before July 8, 1985.

FDA has received comments and recommendations on Pub. L. 98-417 from the Pharmaceutical Manufacturers Association (PMA) and has placed these comments in the public file established by this notice. FDA invites comments on the PMA's submission.

Dated: May 17, 1985.

Mervin H. Shumate,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 85-12537 Filed 5-23-85; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 216

Production Accounting and Auditing System Regulations; Extension of Comment Period

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Proposed rule; extension of comment period.

SUMMARY: This Notice extends the comment period from May 31, 1985, to June 17, 1985, on the proposed rule concerning the information collection requirements necessary to verify that mineral production quantities have been reported and used in calculating royalties due the Government from Federal and Indian leases. This proposed rule was published in the Federal Register on April 1, 1985 (50 FR 12328). The extension of the comment period is in response to requests received from the public to allow additional time for comment.

DATE: Comments by June 17, 1985.

ADDRESS: Comments should be mailed or delivered to Mr. Oris L. Kelm, Chief, Office of Royalty Regulations,

Development and Review, Minerals Management Service, 12303 Sunrise Valley Drive, Mail Stop 800, Reston, Virginia 22091.

FOR FURTHER INFORMATION CONTACT: Mr. Billie Clark, Lakewood, Colorado, (303) 231-3412.

Dated: May 21, 1985

Robert E. Bekht,
Associate Director for Royalty Management

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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Parts 1200, 1202, and 1250

NARA Privacy Act, FOIA, and Official Seal Regulations

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of proposed rulemaking.

SUMMARY: NARA procedures for implementing the Privacy Act of 1974 and the Freedom of Information Act. NARA is a new agency established by Pub. L. 96-497 and must publish regulations on these subjects.

DATE: Comments must be received by June 24, 1985.

ADDRESS: Comments should be sent to: Director, Program Policy and Evaluation Division, National Archives and Records Administration (NARA), Washington, DC 20408.

FOR FURTHER INFORMATION CONTACT: Adrienne C. Thomas or Nancy Allard at 202-523-3214 (FTS 523-3214).

SUPPLEMENTARY INFORMATION: This proposed rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981. As required by the Regulatory Flexibility Act, it is hereby certified that this proposed rule will not have a significant impact on small business entities.

List of Subjects

36 CFR Part 1200

Seals and insignia.

36 CFR Part 1202

Privacy.

36 CFR Part 1250

Freedom of information.

For the reasons set forth in the preamble, it is proposed to amend Chapter XII of Title 36 of the Code of Federal Regulations by adding Parts 1200, 1202, and 1250 to read as follows:

PART 1200—OFFICIAL SEALS

Sec.

1200.1 Definitions.

1200.2 Description and design.

1200.4 Authority to affix seals.

1200.6 Use of the seals.

Authority: 44 U.S.C. 2104(e), 2110(b), 2302.

§ 1200.1 Definitions.

For the purposes of this part—
"Embossing seal" means a display of the form and content of the official seal made on a die so that the seal can be embossed on paper or other medium.

"NARA" means all organizational units of the National Archives and Records Administration.

"Official seal" means the original(s) of the seal showing the exact form, content and color.

"Replica" or "reproduction" means a copy of the official seal displaying the form, content and color.

§ 1200.2 Description and design.

(a) *National Archives and Records Administration seal.* The design is illustrated below and described as follows:

Centered on a disc with a double-line border a solid line rendition of an heraldic eagle displayed holding in its left talon thirteen arrows, in its right talon a branch of olive, bearing on its breast a representation of the shield of the United States and displayed above its head a partially unrolled scroll inscribed with the words LITTERA SCRIPTA MANET one above the other; all within the circumscription NATIONAL ARCHIVES AND RECORDS ADMINISTRATION, with the date 1985 at bottom center.



(b) *National Archives seal.* The design is illustrated below and described as in paragraph (a) of this section, encircled by the circumscription THE NATIONAL ARCHIVES OF THE UNITED STATES, with the date 1934 at the bottom center.



(c) *National Archives Trust Fund Board seal.* The design is illustrated below and described as in paragraph (a) of this section, encircled by the circumscription NATIONAL ARCHIVES TRUST FUND BOARD, with the date 1941 at the bottom center.



§ 1200.4 Authority to affix seals.

The Archivist of the United States and the Archivist's designees are authorized to affix the official seals, embossing seals, replicas and reproductions to appropriate documents, certifications and other material for all purposes authorized by this part.

§ 1200.6 Use of the seals.

(a) The seals are the official emblems of NARA and their use is therefore permitted only as provided in this part.

(b) Use by any person or organization outside NARA may be made only with prior written approval by NARA.

(c) Requests by any person or organization outside NARA for permission to use the seals must be made in writing to the Archivist of the United States, National Archives (N), Washington, DC, 20408, and must