

will be for no more than 90 days. This regulation further requires that FDA publish a notice of any such extension in the **Federal Register**, and that it explain in that notice the basis for the extension, the length of the extension, and the date by which the final rule will be published (§ 101.70(j)(4)(ii)).

In the **Federal Register** of May 14, 1998 (63 FR 26717), FDA published a final rule in part to amend § 101.70 in response to section 302 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 302 of FDAMA amended section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)(A)(i)) to provide, in part, that FDA must publish a final rule on a health claim petition within 540 days of receipt of the petition or FDA is required to provide the relevant House and Senate legislative committees with the reason for failing to do so. Accordingly, FDA amended § 101.70(j)(4)(ii) to state that rulemakings on health claim petitions shall be completed within 540 days of receipt of those petitions. FDA noted that, depending upon how much time the agency uses to file a petition and publish a proposed rule in response to it, the agency may be limited to only one extension under § 101.70(j)(4)(ii), and the extension may be limited to fewer than 90 days (63 FR 26717 at 26718).

In the **Federal Register** of November 10, 1998 (63 FR 62977), FDA proposed adding § 101.82 to authorize the use, on food labels and in food labeling, of health claims on the association between soy protein and reduced risk of coronary heart disease (CHD) (the soy protein proposed rule). In the soy protein proposed rule, the agency presented the rationale for a health claim on this food-disease relationship as provided for under the standard in section 403(r)(3)(B)(i) of the act and 21 CFR 101.14(c) of FDA's regulations. The agency tentatively concluded that, based on the totality of publicly available scientific evidence, soy protein included in a diet low in saturated fat and cholesterol may reduce the risk of CHD. The soy protein proposed rule included qualifying criteria for the purpose of identifying soy protein-containing foods eligible to bear the proposed health claim and a proposed analytical method for assessing compliance with the qualifying criteria. Comments received in response to the soy protein proposed rule have persuaded FDA that the proposed method for assessment of compliance is inadequate for many products. Accordingly, FDA intends to publish, in a separate document, a proposal for an

alternative procedure. This procedure would rely on measurement of total protein and require manufacturers, in certain circumstances, to maintain records that document the amount of soy protein in products and to make these records available to appropriate regulatory officials for inspection and copying upon request.

To publish a final rule regarding a health claim for soy protein and CHD within 270 days of the date of publication of the proposed rule, which was November 10, 1998, the agency should publish the final rule on or before August 6, 1999. However, because of the need to provide for public notice and comment on the reproposal, FDA hereby gives notice that there is cause to extend the period for publication of the final rule for a period of 80 days. FDA will, thus, publish a single final rule in response to both proposals on or before October 25, 1999, which is within 540 days of the date of receipt of the petition.

Dated: July 28, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning and Legislation.*

[FR Doc. 99-19979 Filed 8-3-99; 8:45 am]

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## LIBRARY OF CONGRESS

### Copyright Office

#### 37 CFR Part 201

[Docket No. RM 99-5]

#### Notice and Recordkeeping for Subscription Digital Transmissions

**AGENCY:** Copyright Office, Library of Congress.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Copyright Office of the Library of Congress is proposing to amend the regulation that requires the filing of an initial notice of digital transmissions of sound recordings under statutory license with the Copyright Office to adjust for changes brought about by the passage of the Digital Millennium Copyright Act of 1998.

**DATES:** Comments are due September 3, 1999.

**ADDRESSES:** An original and ten copies of the comments shall be delivered to: Office of General Counsel, Copyright Office, LM-403, James Madison Memorial Building, 101 Independence Avenue, S.E., Washington, D.C. 20559-6000, or mailed to: David O. Carson, General Counsel, Copyright GC/I&R,

P.O. Box 70400, Southwest Station, Washington, D.C. 20024.

**FOR FURTHER INFORMATION CONTACT:** David O. Carson, General Counsel, or Tanya M. Sandros, Attorney Advisor, Copyright GC/I&R, P.O. Box 70400, Southwest Station, Washington, D.C. 20024. Telephone: (202) 707-8380. Telefax: (202) 707-8366.

#### SUPPLEMENTARY INFORMATION:

#### Background

On November 1, 1995, Congress enacted the Digital Performance Act in Sound Recordings Act of 1995 ("DPRA"), Public Law 104-39, 109 Stat. 336 (1995). The DPRA gave to sound recording copyright owners an exclusive right to perform their works publicly by means of a digital audio transmission. 17 U.S.C. 106(6). The new right, however, was subject to certain limitations, including exemptions for certain digital transmissions, 17 U.S.C. 114(d)(1), and the creation of a statutory license for nonexempt digital subscription services. 17 U.S.C. 114(d)(2).

The statutory license requires adherence to regulations under which copyright owners may receive reasonable notice of use of their sound recordings under the statutory license, and under which entities performing the sound recordings shall keep and make available records of such use. 17 U.S.C. 114(f)(2). On May 13, 1996, the Copyright Office initiated a rulemaking proceeding to promulgate regulations to govern the notice and recordkeeping requirements. 61 FR 22004 (May 13, 1996). This rulemaking concluded with the issuance of interim rules to govern the filing of an initial notice of digital transmissions of sound recordings under statutory license, 37 CFR 201.35, and the filing of reports of use of sound recordings under statutory license, 37 CFR 201.36. See 63 FR 34289 (June 24, 1998).

At the time these regulations were announced, only three noninteractive, nonsubscription, digital transmissions services (DMX, Inc., Digital Cable Radio Associates/Music Choice, and Muzak, Inc.) were in operation and considered eligible for the license. Consequently, the Office prescribed a period for filing initial notices such that all existing services, which were already operating in accordance with the section 114 license, had to submit their notices within 45 days of the effective date of the regulation. Section 201.35(f) reads, in part, as follows: "A Service shall file the Initial Notice with the Licensing Division of the Copyright Office prior to the first transmission of sound

recordings under the license, *or within 45 days of the effective date of this regulation.*" (Emphasis added).

Subsequently, the President signed into law the Digital Millennium Copyright Act of 1998 ("DMCA"). Among other things, the DMCA expanded the section 114 compulsory license to allow a nonexempt, eligible nonsubscription transmission service and a pre-existing satellite digital audio radio service to perform publicly a sound recording by means of certain digital audio transmissions, subject to notice and recordkeeping requirements. 17 U.S.C. 114(f).

The notice and recordkeeping requirements found in §§ 201.35 and 201.36 would appear to apply to any service eligible for the section 114 license, including those newly eligible to use the license under the amended provisions of the license. However, these regulations provide no opportunity for a newly eligible nonsubscription transmission service which was in service prior to the passage of the DMCA to make a timely filing of its initial notice of transmission.

Therefore, the Copyright Office is proposing an amendment to § 201.35(f) which would extend the period for filing the initial notice to October 15, 1999, in order to allow the eligible nonsubscription services which were in operation prior to the passage of the DMCA an opportunity to file their initial notice timely. Comments on the extension of the filing period must be filed with the Copyright Office within September 3, 1999.

The Office also recognizes that § 201.36, which prescribes rules detailing how services shall notify copyright owners of the use of their sound recordings, what to include in that notice, and how to maintain and make available such records, does not apply to those services newly eligible for the section 114 license under the DMCA. Currently, § 201.36(c) requires "Reports of Use [to] be served upon Collectives that are identified in the records of the Licensing Division of the Copyright Office as having been designated under the statutory license, either by settlement agreement . . . , or by decision of a Copyright Arbitration Royalty Panel . . . , or by an order of the Librarian . . . ." At this time, no collective has been designated in accordance with any of the methods enumerated in § 201.36(c) for the purpose of collecting royalty fees from the newly eligible services, nor have any rates or terms been set for the use of the license by these services. See 63 FR 65555 (November 27, 1998). The newly

eligible services and the interested copyright owners, however, continue negotiations to reach industry-wide agreement on rates and terms for the expanded section 114 license. In deference to these negotiations, the Office will refrain from initiating at this time a rulemaking proceeding to consider amendments to the recordkeeping regulations.

#### Regulatory Flexibility Act

Although the Copyright Office, located in the Library of Congress which is part of the legislative branch, is not an "agency" subject to the Regulatory Flexibility Act, 5 U.S.C. 601-612, the Register of Copyrights has considered the effect of the proposed amendment on small businesses. The Register has determined that the amendment would not have a significant economic impact on a substantial number of small entities that would require provision of special relief for small entities. The proposed amendment is designed to minimize any significant economic impact on small entities.

#### List of Subjects in 37 CFR Part 201

Copyright.

#### Proposed Regulations

For the reasons set forth in the preamble, part 201 of title 37 of the Code of Federal Regulations is proposed to be amended as follows:

#### PART 201—GENERAL PROVISIONS

1. The authority citation for part 201 continues to read as follows:

**Authority:** 17 U.S.C. 702.

2. Section 201.35(f) is amended by removing the phrase "or within 45 days of the effective date of this regulation." and adding in its place "or by October 15, 1999."

Dated: July 30, 1999.

**Marybeth Peters,**

*Register of Copyrights.*

[FR Doc. 99-19988 Filed 8-3-99; 8:45 am]

BILLING CODE 1410-31-P

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 261

[SW-FRL-6413-1]

#### Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Proposed Exclusion

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule and request for comment.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to grant a petition submitted by BWX Technologies, Inc. (formerly Babcock & Wilcox), to exclude (or "delist") certain solid wastes generated at its Lynchburg, Virginia, facility from the lists of hazardous wastes contained in Subpart D of Title 40 of the Code of Federal Regulations Part 261. This action responds to a "delisting" petition submitted pursuant to 40 CFR 260.20, which allows any person to petition the Administrator to modify or revoke any provision of 40 CFR Parts 260 through 266, 268, and 273, and pursuant to 40 CFR 260.22, which specifically provides generators the opportunity to petition the Administrator to exclude a waste on a "generator-specific" basis from the hazardous waste lists. This proposed decision is based on an evaluation of waste-specific information provided by the petitioner. If this proposed decision is finalized, the petitioned waste will be excluded from the requirements of the hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA).

**DATES:** EPA is requesting public comments on this proposed decision. Comments will be accepted until September 20, 1999. Comments postmarked after the close of the comment period will be stamped "late."

Any person may request a hearing on this proposed decision by filing a request by August 19, 1999. The request must contain the information prescribed in 40 CFR 260.20(d).

**ADDRESSES:** Two copies of any comments should be sent to David M. Friedman, Technical Support Branch (3WC11), U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA, 19103-2029.

Requests for a hearing should be addressed to John A. Armstead, Director, Waste and Chemicals Management Division (3WC00), U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA, 19103-2029.

The RCRA regulatory docket for this proposed rule is located at the offices of U.S. EPA Region III, 1650 Arch Street, Philadelphia, PA, 19103-2029, and is available for viewing from 8:30 a.m. to 5:00 p.m., Monday through Friday, excluding Federal holidays. Call David M. Friedman at (215) 814-3395 for appointments. The public may copy material from the regulatory docket at \$0.15 per page. The docket for this proposed rule is also located at the offices of the Campbell County Administrator's Office, P.O. Box 100,