

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 606

[Docket No. 2003N-0211]

#### Revisions to Labeling and Storage Requirements for Blood and Blood Components, Including Source Plasma; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a proposed rule that proposed to revise the labeling and storage requirements for certain human blood and blood components, including Source Plasma (proposed labeling and storage rule). The proposed rule appeared in the *Federal Register* of July 30, 2003 (68 FR 44678). The proposed regulation included a paragraph that FDA did not intend to publish. This document corrects that error by removing the incorrect paragraph from the proposed rule.

**DATES:** Submit written or electronic comments on the proposed rule by October 28, 2003.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD, 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Sharon Carayiannis, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:** The proposed rule that published in the *Federal Register* of July 30, 2003, inadvertently included § 606.121(c)(13) in the proposed text of the regulation (68 FR 44678 at 44686). As discussed in the proposed labeling and storage rule (68 FR 44678 at 44682), FDA issued a related proposed rule entitled "Bar Code Label Requirements for Human Drug Products and Blood" (proposed bar code rule) in the *Federal Register* of March 14, 2003 (68 FR 12499). The proposed bar code rule would amend § 606.121(c)(13) to require certain human drug and biological product labels to bear bar codes and also would require the use of machine-readable information on container labels for blood and blood components intended

for transfusion. FDA did not intend to propose to revise § 606.121(c)(13) in the proposed labeling and storage rule, and the agency is removing that paragraph to eliminate any confusion that might occur.

In FR Doc. 03-19289, appearing on page 44678, in the *Federal Register* of July 30, 2003, the following correction is made:

#### § 606.121 [Corrected]

1. On page 44686, in the third column, § 606.121 *Container label* is corrected by removing paragraph (c)(13).

Dated: October 20, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-27012 Filed 10-24-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 920

[MD-051-FOR]

#### Maryland Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

**ACTION:** Proposed rule; public comment period and opportunity for public hearing on proposed amendments.

**SUMMARY:** We are announcing receipt of a proposed amendment to the Maryland regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The program amendment consists of changes to the Code of Maryland Regulations (COMAR) to incorporate various changes related to: augering, lands eligible for re-mining, required written findings, and topsoil handling.

**DATES:** We will accept written comments on this amendment until 4 p.m. (local time), on November 26, 2003. If requested, we will hold a public hearing on the amendment on November 21, 2003. We will accept requests to speak at a hearing until 4 p.m. (local time), on November 12, 2003.

**ADDRESSES:** You should mail or hand-deliver written comments and requests to speak at the hearing to Mr. George Rieger, at the address listed below.

You may review copies of the Maryland program, this amendment, a listing of any scheduled public hearings, and all written comments received in

response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting the Appalachian Regional Coordinating Center.

Mr. George Rieger, Field Office Director, Office of Surface Mining Reclamation and Enforcement, Appalachian Regional Coordinating Center, 3 Parkway Center, Pittsburgh, PA 15220, (412) 937-2153.

Mr. C. Edmon Larrimore, Program Manager, Mining Program, 1800 Washington Boulevard, Baltimore, Maryland 21230, (410) 537-3000, or 1-800-633-6101.

**FOR FURTHER INFORMATION CONTACT:** Mr. George Rieger, Telephone: (412) 937-2153. Internet: [grieger@osmre.gov](mailto:grieger@osmre.gov).

#### SUPPLEMENTARY INFORMATION:

- I. Background on the Maryland Program
- II. Description of the Proposed Amendment
- III. Public Comment Procedures
- IV. Procedural Determinations

#### I. Background on the Maryland Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, "a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act \* \* \*; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act." See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Maryland program on December 1, 1980. You can find background information on the Maryland program, including the Secretary's findings, the disposition of comments, and conditions of approval in the December 1, 1980, *Federal Register* (45 FR 79431). You can also find later actions concerning Maryland's program and program amendments at 30 CFR 920.12, 920.15 and 920.16.

#### II. Description of the Proposed Amendment

By letter dated September 16, 2003, Maryland sent us a proposed amendment to its program (Administrative Record Number MD-585-00) under SMCRA (30 U.S.C. 1201 *et seq.*). Maryland sent the amendment to include changes made at its own initiative.