

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.

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.

The provisions of COMAR that Maryland proposes to revise are as follows: COMAR, 26.20.03.07 Augering, A. and B., 26.20.03.11 Lands Eligible for Remining, A., B., (1), (2), C., and D., 26.20.05.01 Required Written Findings, A., B., C., L., (1), (2), and (3), and 26.20.25.02 Topsoil Handling D. The specific amendments to COMAR are identified below.

26.20.03.07 Augering.

Maryland proposes to recode the first section A. and add section B. which states "No permit shall be issued for any augering operations unless the Bureau finds, in writing, that the operation meets all other requirements of this subtitle and will be conducted in compliance with COMAR 26.20.24.01".

26.20.03.11 Lands Eligible for Remining.

Maryland proposes to add sections which state:

A. This regulation applies to any person who conducts or intends to conduct a surface coal mining operation on lands eligible for remining.

B. Any application for a permit under this regulation shall be made according to all requirements of this subtitle applicable to surface coal mining and reclamation operations. In addition, the application shall:

(1) To the extent not otherwise addressed in the permit application, identify potential environmental and safety problems related to prior mining activities at the site that could be reasonably anticipated to occur; and

(2) With regard to potential environmental and safety problems referred to in section B(1) of this regulation, describe the mitigative measures that will be taken to ensure that the applicable reclamation requirements of the Regulatory Program can be met.

C. The identification of the environmental and safety problems required under section B(1) of this regulation shall include visual observations at the site, a record review of past mining at the site, and environmental sampling tailored to current site conditions.

D. The requirements of the regulation shall not apply after September 30, 2004.

26.20.05.01 Required Written Findings.

"A, and may not" are deleted and this section is revised to read, "No permit application or application for a significant revision of a permit shall be approved unless the application affirmatively demonstrates and the Bureau finds, in writing, on the basis of information set forth in the application, or information otherwise available and

documented in the approval under COMAR 26.20.04.11 A., the following:"

A. "Complies" is deleted and this section now reads, "The permit application is complete and accurate and the applicant has complied with all requirements of the Regulatory Program;"

B. The words "Surface coal mining and" as well as "mining and" are deleted and the section is revised to read, "The applicant has demonstrated that reclamation operations, as required by the Regulatory Program, can be feasibly accomplished under the reclamation plan contained in the application;"

C. The phrases "has been made an" and "have been made" have been deleted and the section now reads, "The Bureau has made an assessment of the probable cumulative impacts of all anticipated coal mining in the cumulative impact area on the hydrologic balance and has determined that the operations proposed under the application have been designed to prevent material damage to the hydrologic balance outside the proposed permit area;"

D.-K. (text unchanged)

L. The sentence, "The activities are conducted so as to reasonably maximize the use of coal, while using the best appropriate technology currently available to maintain environmental integrity, so that the probability of re-affecting the land in the future by strip or underground mining operations is minimized." is deleted and the section is revised to read, "For permits issued under COMAR 26.20.03.11, the permit application must contain:"

(1) Land eligible for remining;

(2) An identification of the potential environmental and safety problems related to the prior mining activities which could reasonably be anticipated to occur at the site; and

(3) Mitigation plans to sufficiently address these potential environmental safety problems so that reclamation as required by the applicable requirements of the Regulatory Program can be accomplished.

26.20.25.02 Topsoil Handling.

A.-C. (text unchanged)

D. The word "Topsoil", the phrase "in the amounts determined by soil tests", and the fragment and sentence "surface soil layer so that it supports the approved post mining land use and meets the revegetative requirements. All soil tests shall be performed by a qualified laboratory or person using standard methods approved by the bureau." all have been deleted. The section now reads as follows:

Nutrients and Soil Amendments.

Nutrients and soil amendments shall be applied to the initially redistributed material when necessary to establish the vegetative cover.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the Maryland program.

Written Comments

Send your written or electronic comments to OSM at the address given above. Your written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of your recommendations. We may not consider or respond to your comments when developing the final rule if they are received after the close of the comment period (see **DATES**). We will make every attempt to log all comments into the administrative record, but comments delivered to an address other than the Appalachian Regional Coordinating Center may not be logged in.

Electronic Comments

Please submit Internet comments as an ASCII, Word file avoiding the use of special characters and any form of encryption. Please also include "Attn: SATS NO. MD-051-FOR" and your name and return address in your Internet message. If you do not receive a confirmation that we have received your Internet message, contact the Appalachian Regional Coordinating Center at (412) 937-2153.

Availability of Comments

We will make comments, including names and addresses of respondents, available for public review during normal business hours. We will not consider anonymous comments. If individual respondents request confidentiality, we will honor their request to the extent allowable by law. Individual respondents who wish to withhold their name or address from public review, except for the city or town, must state this prominently at the beginning of their comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under

FOR FURTHER INFORMATION CONTACT by 4 p.m. (local time), on November 12, 2003. If you are disabled and need special accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the Administrative Record.

IV. Procedural Determinations

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

Executive Order 12866—Regulatory Planning and Review

This rule is exempt from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and

promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

Executive Order 13132—Federalism

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to “establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.” Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be “in accordance with” the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations “consistent with” regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. The basis for this determination is our decision is on a State regulatory program and does not involve a Federal regulation involving Indian lands.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is: (1) Considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not

expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of \$100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the analysis performed under various laws and executive orders for the counterpart Federal regulations.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or

tribal governments or the private sector of \$100 million or more in any given year. This determination is based upon the analysis performed under various laws and executive orders for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 2, 2003.

Brent Wahlquist,

Regional Director, Appalachian Regional Coordinating Center.

[FR Doc. 03-27044 Filed 10-24-03; 8:45 am]

BILLING CODE 4310-05-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 926

[MT-024-FOR]

Montana 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 amendment.

SUMMARY: We are announcing receipt of a proposed amendment to the Montana regulatory program (hereinafter, the "Montana program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Montana proposes to make editorial and substantive revisions to the Montana Strip and Underground Mine Reclamation Act (MSUMRA) provisions in the Montana Code Annotated (MCA) that pertain to: State policy and findings concerning mining and reclamation; definitions; the time required to approve or disapprove minor permit revisions; permit application requirements, including determinations of probable hydrologic consequences and land use; requirements to protect the hydrologic balance; area mining, post-mine land use, and wildlife enhancement; revegetating disturbed areas; timing of reclamation; standards for successful revegetation; making vegetation the landowner's property after bond release; jurisdictional venue in right-of-entry actions; transfer of revoked permit; and mandamus. The State also proposes to add new provisions to the MSUMRA for: Revising applications for permits, permit amendments, and permit revisions; codifying the changes proposed in the amendment; clauses for severability, saving, and contingent

voidness; and a delayed effective date for the proposed changes. Montana intends to revise its program to incorporate the additional flexibility afforded by the revised Federal regulations and SMCRA, as amended, to provide additional clarification, and to improve operational efficiency.

This document gives the times and locations that the Montana program and proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

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

ADDRESSES: You should mail or hand-deliver written comments and requests to speak at the hearing to Guy Padgett at the address listed below.

You may review copies of the Montana 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 OSM's Casper Field Office.

Guy Padgett, Director, Casper Field Office, Office of Surface Mining, Federal Building, 100 East B Street, Casper, Wyoming 82601-1918, Telephone: (307) 261-6550, e-mail: gpadgett@osmre.gov.

Neil Harrington, Chief, Industrial and Energy Minerals Bureau, Coal and Uranium Program, Department of Environmental Quality, Phoenix Building, 2209 Phoenix Avenue, P.O. Box 200902, Helena, Montana 59620-0902, Telephone: (406) 444-4973, e-mail: neharrington@state.mt.us.

FOR FURTHER INFORMATION CONTACT: Guy Padgett, Casper Field Office Director; telephone: (307) 261-6550; e-mail: gpadgett@osmre.gov.

SUPPLEMENTARY INFORMATION:

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

I. Background on the Montana 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 this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this 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 Montana program on April 1, 1980. You can find background information on the Montana program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Montana program in the April 1, 1980, **Federal Register** (45 FR 21560). You can also find later actions concerning Montana's program and program amendments at 30 CFR 926.15, 926.16, and 926.30.

II. Description of the Proposed Amendment

By letter dated July 29, 2003, Montana sent us a proposed amendment to its program (SATS MT-024-FOR; Administrative Record No. MT-21-1) under SMCRA (30 U.S.C. 1201 *et seq.*). Montana sent the amendment to include changes made at its own initiative. The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES**.

The provisions of the Montana Strip and Underground Mine Reclamation Act that Montana proposes to add and/or revise are as follows.

82-4-202, Policy—Findings

Making editorial changes to State policy and findings concerning the environment, mining and reclamation and adding new policy and findings statements.

82-4-203, Definitions

Adding or revising the terms "adjacent area," "approximate original contour," "cropland," "developed water resources," "ephemeral drainageway," "fish and wildlife habitat," "forestry," "grazing land," "higher or better uses," "hydrologic balance," "industrial or commercial," "intermittent stream," "land use," "material damage," "pastureland," "perennial stream," "reclamation," "recreation," "reference area," "residential," "restore or restoration," "surface owner," and "wildlife habitat enhancement feature"; and recodifying defined terms and making editorial changes in the wording of several terms.