

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

21 CFR Parts 606, 610, 630, 640, 660, 820, and 1270

[Docket No. 2006N-0221]

#### Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use; Extension of Comment Period

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

**ACTION:** Proposed rule; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to August 4, 2008, the comment period for the proposed rule that appeared in the **Federal Register** of November 8, 2007 (72 FR 63416). In the proposed rule, FDA had requested comments by February 6, 2008. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** Submit written and electronic comments by August 4, 2008.

**ADDRESSES:** You may submit comments, identified by Docket No. 2006N-0221, by any of the following methods:  
*Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
  - Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- Written Submissions*

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

*Instructions:* All submissions received must include the agency name and Docket No(s), and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Brenda R. Friend, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of November 8, 2007 (72 FR 63416), FDA published a proposed rule with a 90-day comment period to request comments on the proposed rule. The proposed rule would establish regulations for blood and blood components, including Source Plasma and Source Leukocytes, to add donor requirements that are consistent with current practices in the blood industry, and to more closely align the regulations with current FDA recommendations.

The agency has received requests for a 180-day extension of the comment period for the proposed rule. Each

request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 180 days, until August 4, 2008. The agency believes that a 180-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

##### **II. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: January 2, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E8-297 Filed 1-10-08; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 931

[Docket ID: OSM-2007-0021; SATS No. NM-047-FOR]

#### New Mexico Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, 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 New Mexico regulatory program (hereinafter, the "New Mexico program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). New Mexico is proposing additions of and revisions to the New Mexico Annotated Code (NMAC) to improve and clarify the public notification process during permitting actions, to correct outdated citations, to comply with formatting requirements for New Mexico administrative law; the revisions also include non-substantive editorial changes. New Mexico revised its program to provide additional safeguards, clarify ambiguities, and achieve stylistic consistency.

This document gives the times and locations that the New Mexico 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 standard time February 11, 2008. If requested, we will hold a public hearing on the amendment on February 5, 2008. We will accept requests to speak until 4 p.m., mountain standard time on January 28, 2008.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Mail/Hand Delivery/Courier:* Bob Postle, Branch Chief, Field Operations, Program Support Division, Western Region, Office of Surface Mining, Reclamation, and Enforcement, 505 Marquette Ave. NM Suite 1200, Albuquerque, NM 87102, Telephone: (505) 248-5070, Internet address: [bpostle@osmre.gov](mailto:bpostle@osmre.gov).

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. The proposed rule is listed under the agency name "OFFICE OF SURFACE MINING RECLAMATION AND ENFORCEMENT." The proposed rule has been assigned Docket ID: OSM-2007-0021.

If you would like to submit comments through the Federal eRulemaking Portal, go to [www.regulations.gov](http://www.regulations.gov) and do the following. Click on the "Advanced Docket Search" button on the right side of the screen. Type in the Docket ID OSM-2007-0021 and click the "Submit" button at the bottom of the page. The next screen will display the Docket for NM-047-FOR. If you click

on OSM-2007-0021, you can view the proposed rule, add comments, and view any comments submitted by other persons.

*Docket:* You may access the docket for this rulemaking at [www.regulations.gov](http://www.regulations.gov). Search for Docket ID: OSM-2007-0021.

At [www.regulations.gov](http://www.regulations.gov), you may review and print a copy of the New Mexico program amendment, a listing of any scheduled public hearings, and all written comments received in response to this document. The information may also be obtained 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 Albuquerque Area Office.

Bob Postle, Branch Chief, Field Operations, Program Support Division, Western Region, Office of Surface Mining Reclamation and Enforcement, 505 Marquette Ave. NM Suite 1200, Albuquerque, NM 87102, Telephone: (505) 248-5070.

Bill Brancard, Director, Mining and Minerals Division, New Mexico Energy, Minerals, and Natural Resources Department, 1220 South St. Francis Drive, Sante Fe, New Mexico 87505, Telephone: (505) 476-3400.

**FOR FURTHER INFORMATION CONTACT:** Bob Postle, Telephone: (505) 248-5070, Internet address: [bpostle@osmre.gov](mailto:bpostle@osmre.gov).

**SUPPLEMENTARY INFORMATION:**

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

**I. Background on the New Mexico 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 (a)(7). On the basis of these criteria, the Secretary of the Interior conditionally approved the New Mexico program on December 31, 1980. You can find background information on the New Mexico program, including the Secretary's findings, the disposition of comments, and conditions of approval in the December 31, 1980, **Federal Register** (45 FR 86459). You can also find later actions concerning New

Mexico's program and program amendments at 30 CFR 931.10, 931.11, 931.13, 931.15, 931.16, and 931.30.

**II. Description of the Proposed Amendment**

By letter dated November 28, 2007, New Mexico sent us a proposed amendment to its program (SATS No. NM-047-FOR) under SMCRA (30 U.S.C. 1201 *et seq.*). New Mexico proposed this amendment at its own initiative. The full text of the program amendment is available for you to read at the locations listed above under

**ADDRESSES.**

New Mexico proposes revisions to the New Mexico Annotated Code (NMAC) 19.8. New Mexico proposed the revisions to improve and clarify the public notification process during permitting actions, correct outdated citations, and comply with formatting requirements for New Mexico administrative law; these revisions include many non-substantive editorial changes which are not described below.

Specifically, New Mexico proposes the following substantive revisions:

NMAC 19.8.7.701.F requires the permit application to include the owner of record and residents of dwellings and structures within one-half mile of any part of the proposed permit area (the previous requirement was limited to properties contiguous to any part of the proposed permit area).

NMAC 19.8.8.812.D requires, consistent with the above proposed rule, that all dwellings and structures within one-half mile of the proposed permit area are included on the permit application maps (the previous rule required that only dwellings and structures within 1000 feet be included on the maps).

NMAC 19.8.11.1100.B(1) requires that notice of a permit application or permit revision be provided by at least three of the following methods: mailing a notice to the owners of record within one-half mile of the proposed permit area, posting a notice in four publicly accessible places, publishing a notice in a newspaper, and radio broadcasted public service announcements. If there is a significant non-English speaking population living within the area, a method to reach these people must be used.

NMAC 19.8.11.1100.D(5) requires that written notifications shall be mailed to persons on a list maintained by the Director.

NMAC 19.8.11.1100.E(3) requires that written notifications be posted on a Web site after an application is received.

NMAC 19.8.11.1100.F require that the Director shall hold a public meeting

within 60 days of receipt of a completed application for a new permit or a permit revision.

### 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 New Mexico program.

#### Written Comments

Send your written or electronic comments to OSM at one of the two addresses given above (see **ADDRESSES**). Your comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of your recommendations. We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than the two listed above will be included in the docket for this rulemaking and considered.

#### Availability of Comments

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

#### Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., mountain standard time, on January 28, 2008. If you are disabled and need reasonable accommodation 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 the hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at a 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 are 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 docket for this rulemaking.

### IV. Procedural Determinations

#### Executive Order 12630—Takings

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

#### Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

#### Executive Order 12988—Civil Justice Reform

The Department of the Interior conducted the reviews required by section 3 of Executive Order 12988 and 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.

#### 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 rule does not involve or affect Indian Tribes in any way.

#### 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 on Federal regulations for which an analysis was prepared and certification made that such regulations would not have a significant economic effect on 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 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 prepared for the 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 fact that the State submittal, which is the subject of this rule, is based on Federal regulations for which an analysis was prepared and a determination made that the Federal regulations did not impose an unfunded mandate.

**List of Subjects in 30 CFR Part 931**

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 7, 2007.

**Allen D. Klein,**

*Regional Director, Western Regional Coordinating Center.*

[FR Doc. E8-359 Filed 1-10-08; 8:45 am]

**BILLING CODE 4310-05-P**

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 224**

[Docket No. 071128765-7769-01]

**RIN 0648-AW32**

**Endangered and Threatened Wildlife and Plants; Proposed Endangered Status for Black Abalone**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** We, NMFS, have completed a review of the status of black abalone (*Haliotis cracherodii*) under the Endangered Species Act (ESA). After reviewing the best scientific and commercial information available, evaluating threats facing the species, and considering efforts being made to protect black abalone, we have concluded that the species is in danger of extinction throughout all of its range and are proposing to list the species as endangered under the ESA. This proposal is based on information indicating that: the disease known as withering syndrome has spread to areas throughout the range of the species, has been responsible for the local extirpation of populations throughout a large part of the species' range, and threatens remaining black abalone populations; low adult densities below the critical threshold density required for successful fertilization exist throughout a large part of the species' range; and, a number of interacting factors (e.g., suboptimal water temperatures, reduced genetic diversity, and illegal harvest) may further hamper natural recovery of the species. A critical habitat designation is being considered and may be proposed in a subsequent **Federal Register** notice. If the proposed listing is finalized, a recovery plan will be prepared and implemented.

**DATES:** Comments on this proposal must be received by April 10, 2008. Public hearing (s) will be held promptly if any person so requests by February 25, 2008. Notice of the location (s) and time(s) of any such hearing(s) will be published in the **Federal Register** not less than 15 days before the hearing(s) is(are) held.

**ADDRESSES:** You may submit comments, identified by [RIN 0648-AW32], by any one of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal <http://www.regulations.gov>.

- Facsimile (fax): 562-980-4027, Attn: Melissa Neuman.

- Mail: Submit written comments to Chief, Protected Resources Division, Southwest Region, National Marine Fisheries Service, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802-4213.

Instructions: All comments received are a part of the public record and will generally be posted to <http://www.regulations.gov> without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

We will accept anonymous comments. Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

A draft black abalone status review report and other reference materials regarding this determination can be obtained via the Internet at: <http://www.nmfs.noaa.gov>. The draft status review report and list of references are also available by submitting a request to the Assistant Regional Administrator, Protected Resources Division, Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802-4213.

**FOR FURTHER INFORMATION CONTACT:** Melissa Neuman, NMFS, Southwest Region (562) 980-4115; or Lisa Manning, NMFS, Office of Protected Resources (301) 713-1401.

**SUPPLEMENTARY INFORMATION:**

**Background**

Black abalone was added to the National Marine Fisheries Service's (NMFS') Candidate Species list on June 23, 1999 (64 FR 33466) and remained on this list after NMFS redefined the term "candidate species" on April 15, 2004 (69 FR 19975). We initiated an informal ESA status review of black abalone on July 15, 2003, and formally announced initiation of a status review on October 17, 2006 (71 FR 61021), at the same time soliciting information from the public. On December 27, 2006, we received a petition from the Center for Biological Diversity (CBD) to list black abalone as either an endangered or threatened species under the ESA and to designate critical habitat for the species concurrently with any listing determination. We published a 90-day