

**List of Subjects in 17 CFR Part 230**

Reporting and recordkeeping requirements, Securities.

**Text of Rule and Form Proposals**

For the reasons set out in the preamble, title 17, chapter II of the Code of Federal Regulations is proposed to be amended as follows:

**PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933**

1. The citation for Part 230 continues to read in part as follows:

**Authority:** 15 U.S.C. 77b, 77f, 77g, 77h, 77j, 77r, 77s, 77sss, 78c, 78d, 78l, 78m, 78n, 78o, 78w, 78ll(d), 79t, 80a-8, 80a-24, 80a-29, 80a-30, and 80a-37, unless otherwise noted.  
\* \* \* \* \*

**§ 230.502 [Amended]**

2. By amending the introductory text of paragraph (d) of § 230.502 by revising the words "Except as provided in § 230.504(b)(1), securities" to read "Securities".

3. By revising § 230.504(b)(1) to read as follows:

**§ 230.504 Exemption for limited offerings and sales of securities not exceeding \$1,000,000.**  
\* \* \* \* \*

(b) *Conditions to be met.*—(1) *General conditions.* To qualify for exemption under this § 230.504, offers and sales must satisfy the terms and conditions of §§ 230.501 and 230.502(a) and (d).  
\* \* \* \* \*

Dated: May 21, 1998.

By the Commission.

**Margaret H. McFarland,**

*Deputy Secretary.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 809 and 864**

[Docket No. 97N-0135]

**Medical Devices; Hematology and Pathology Devices; Reclassification; Restricted Devices; OTC Test Sample Collection Systems for Drugs of Abuse Testing; Public Hearing**

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

**ACTION:** Notification of public hearing on proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a

public hearing on a proposed rule to reclassify over-the-counter (OTC) test sample collection systems for drugs of abuse testing. The purpose of the public hearing is to solicit input on the proposed rule in addition to comments being submitted to the docket. The information obtained at the hearing will assist FDA in its preparation of a final rule.

**DATES:** The public hearing will be held on June 19, 1998, from 9 a.m. to 5 p.m. Written notices of participation should be filed by June 8, 1998. Submit written comments by July 5, 1998.

**ADDRESSES:** The public hearing will be held at the Food and Drug Administration, 5600 Fishers Lane, conference rooms D and E, Rockville, MD 20857. Submit written notices of participation and written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Steven I. Gutman, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-3084.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 5, 1998 (63 FR 10792), FDA published a proposed rule to reclassify OTC test sample collection systems for drugs of abuse testing. FDA has determined that a public hearing on the proposed rule is warranted. The hearing will be directed by William B. Schultz, Deputy Commissioner for Policy, FDA. To the extent possible, oral testimony should address the issues identified in the proposed rule (63 FR 10792). The procedures governing the hearing are those applicable to a public hearing before the Commissioner of Food and Drugs under 21 CFR part 15.

Interested persons who wish to participate may, on or before June 8, 1998, submit a notice of participation to the Dockets Management Branch (address above). All notices submitted should be identified with the docket number found in brackets in the heading of this document and should contain the name, address, telephone number, business affiliation of the person requesting to make a presentation, a brief summary of the presentation, and the approximate time requested for the presentation.

Individuals or groups having similar interests are requested to consolidate their comments and present them through a single representative. FDA will allocate the time available for the

hearing among the persons who properly file a notice of appearance.

After reviewing the notice of participation and accompanying information, FDA will schedule each appearance and notify each participant by mail or telephone of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. FDA may require joint presentations by persons with common interests. The schedule of the public hearing will be available at the hearing and it will be placed on file in the Dockets Management Branch following the hearing.

The administrative record of the proposed regulation will be open for 15 days after the hearing to allow comments on matters raised at the hearing. Persons who wish to provide additional materials for consideration are to file these materials with the Dockets Management Branch (address above) during that period.

The hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officers and panel members may question any person during or at the conclusion of their presentation.

Dated: May 20, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-14048 Filed 5-27-98; 8:45 am]

BILLING CODE 4160-01-F

**DEPARTMENT OF THE INTERIOR**

**Office of Surface Mining Reclamation and Enforcement**

**30 CFR Part 936**

[SPATS No. OK-022-FOR]

**Oklahoma Regulatory Program**

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

**ACTION:** Proposed Rule; reopening and extension of public comment period on proposed amendment.

**SUMMARY:** OSM is announcing receipt of revisions and additional explanatory information pertaining to a previously proposed amendment to the Oklahoma regulatory program (hereinafter referred to as the "Oklahoma program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The revisions and additional explanatory information pertain to normal

husbandry practices and non-augmentative reclamation activities. The amendment is intended to revise the Oklahoma program to improve operational efficiency.

**DATES:** Written comments must be received by 4:00 p.m., c.d.t., June 12, 1998.

**ADDRESSES:** Written comments should be mailed or hand delivered to Michael C. Wolfrom, Director, Tulsa Field Office at the address listed below.

Copies of the Oklahoma program, the proposed amendment, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Tulsa Field Office.

**FOR FURTHER INFORMATION CONTACT:** Michael C. Wolfrom, Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 5100 East Skelly Drive, Suite 470, Tulsa, Oklahoma 74135-6547, Telephone: (918) 581-6430.

Oklahoma Department of Mines, 4040 N. Lincoln Blvd., Suite 107, Oklahoma City, Oklahoma 73105, Telephone: (405) 521-3859.

**FOR FURTHER INFORMATION CONTACT:** Michael C. Wolfrom, Director, Tulsa Field Office, Telephone: (918) 581-6430.

**SUPPLEMENTARY INFORMATION:**

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

**I. Background on the Oklahoma Program**

On January 19, 1981, the Secretary of the Interior conditionally approved the Oklahoma program. Background information on the Oklahoma program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the January 19, 1981, **Federal Register** (46 FR 4902). Subsequent actions concerning the Oklahoma program can be found at 30 CFR 936.15 and 936.16.

**II. Discussion of the Proposed Amendment**

By letter dated July 3, 1997 (Administrative Record No. OK-978), Oklahoma submitted a proposed amendment to its program pursuant to SMCRA. Oklahoma submitted the proposed amendment at its own initiative. Oklahoma proposed to amend the Oklahoma Administrative Code (OAC) for surface mining operations at

OAC 460:20-43-46(c)(4) and underground mining operations at OAC 460:20-45-46(c)(4) by adding criteria for normal husbandry practices and non-augmentative reclamation activities within the State.

OSM announced receipt of the proposed amendment in the August 8, 1997, **Federal Register** (62 FR 42715) and invited public comment on its adequacy. The public comment period ended September 8, 1997.

During its review of the amendment, OSM identified concerns in OAC 460:20-43-46(c)(4) and 460:20-45-46(c)(4) relating to the requirement that OSM approve normal husbandry practices used in the State; OAC 460:20-43-46(c)(4)(D) and 460:20-45-46(c)(4)(D) relating to a discrepancy between the proposed language and Appendix R of Oklahoma's Bond Release Guidelines on the repair of rills and gullies; and OAC 460:20-43-46(c)(4)(E) and 460:20-45-46(c)(4)(E) relating to the non-augmentative reclamation activities proposed for temporary structures. OSM notified Oklahoma of the concerns by letters dated November 19, 1997, and March 23, 1998, and via telephone conferences on February 10, 1998 and March 19, 1998 (Administrative Record Nos. OK-978.05, OK-978.10, OK-978.06, and OK-978.09, respectively). Oklahoma responded in letters dated March 4, 1998, April 22, 1998, April 30, 1998, and May 13, 1998 (Administrative Record Nos. OK-978.08, OK-978.13, OK-978.14, and OK-978.11, respectively), by submitting a revised amendment and additional explanatory information.

Oklahoma is proposing (1) normal husbandry practices for reseeded, fertilizing, liming, weed and pest control, mulching, irrigation, pruning, transplanting and replanting trees and shrubs, and repair of rills and gullies and (2) non-augmentative reclamation activity practices for removal and reclamation of temporary structures. Summarized below by regulation numbers is a discussion of the revisions and additional explanatory information submitted by Oklahoma.

1. Oklahoma revised the first sentence of OAC 460:20-43-46(c)(4) and 460:20-45-46(c)(4) by adding the language "and non-augmentative reclamation activities." The revised sentence reads as follows:

The Department and the Office of Surface Mining have approved selective husbandry practices and non-augmentative reclamation activities that, when accomplished in accordance with (A) through (G) below, do not extend the period of responsibility for revegetation success and bond liability.

In its letter dated April 22, 1998, Oklahoma stated that it understands that any normal husbandry practice(s) not included in its March 4, 1998, revised amendment will be submitted to OSM for approval in accordance with 30 CFR 732.17. In order to support its proposed regulations at OAC 460:20-43-46(c)(4) and 460:20-45-46(c)(4), Oklahoma submitted several guidelines published by the Oklahoma State University and the Natural Resources Conservation Service on the types of agricultural practices that will not be considered augmentative.

2. Oklahoma revised the third sentence of OAC 460:20-43-46(c)(4)(A), pertaining to surface mining operations, by adding the language "identified at subsection 460:20-43-46(c)(4)(E)." The revised sentence reads as follows:

Removal and reclamation of temporary structures identified at subsection 460:20-43-46(c)(4)(E) would not be considered augmentation.

3. Oklahoma revised the third sentence of OAC 460:20-45-46(c)(4)(A), pertaining to underground mining operations, by adding the language "identified at subsection 460:20-45-46(c)(4)(E)." The revised sentence reads as follows:

Removal and reclamation of temporary structures identified at subsection 460:20-45-46(c)(4)(E) would not be considered augmentation.

4. Oklahoma revised OAC 460:20-43-46(c)(4)(D) and 460:20-45-46(c)(4)(D) by removing the language "during the initial establishment" from the third and fifth sentence and replacing the sixth and seventh sentence with the following language:

After initial vegetation establishment, ODOM defines the treatment of rills and gullies requiring permanent reseeded of more than 10 acres in a contiguous block or 10% of a permit area initially seeded during a single year to be an augmentative practice because of the potential for delayed seeding of large areas to reduce the probability of revegetation success.

Oklahoma submitted copies of the Natural Resources Conservation Service (NRCS) guidelines for repair of rills and gullies entitled "State Standard and Specifications for Critical Area Treatment" and "Critical Area Planting" to support its proposed regulations at OAC 460:20-43-46(c)(4)(D) and 460:20-45-46(c)(4)(D).

5. Oklahoma revised OAC 460:20-43-46(c)(4)(E) and 460:20-45-46(c)(4)(E), by changing the word "haulroads" to "roads" and adding the language "remaining after a Phase I Bond Release approval" to its previously proposed

provision. The revised regulations read as follows:

Liming, fertilization, mulching, seeding or stocking following the reclamation of any temporary roads remaining after a Phase I Bond Release approval, temporary sediment or hydraulic control structures, areas disturbed by the installation or removal of oil and gas wells or utility lines, and areas where the vegetation was disturbed by vehicular traffic not under the control of the permittee will not be considered augmentation.

In its letter of April 22, 1998, Oklahoma clarified that its proposed regulations at OAC 460:20-43-46(c)(4)(E) and 460:20-45-46(c)(4)(E) do not approve the reclamation of temporary haul roads after Phase I approval as a non-augmentative practice.

6. Oklahoma is proposing to delete Appendix R and to revise Appendix A of its Bond Release Guidelines. Appendix R contains Oklahoma's currently approved guidelines for the repair of rills and gullies, and it is being replaced by Oklahoma's proposed regulations at OAC 460:20-43-46(c)(4)(D) and 460:20-45-46(c)(4)(D). The definition for "Augmentation" in Appendix A is being revised by replacing the reference to Appendix R with a reference to OAC 460:20-43-46(c)(4) and 460:20-45-46(c)(4). The definition of "Initial Establishment of Permanent Vegetative Cover" is being deleted from Appendix A.

### III. Public Comment Procedures

OSM is reopening the comment period on the proposed Oklahoma program amendment to provide the public an opportunity to reconsider the adequacy of the proposed amendment in light of the additional materials submitted. In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Oklahoma program.

### Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Tulsa Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

### IV. Procedural Determinations

#### Executive Order 12866

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

#### Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, 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 since each such 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 30 CFR 730.11, 732.15, and 732.17(h)(10), decision 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.

#### National Environmental Policy Act

No environmental impact statement is required for this rule since 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 has determined 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. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. 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.

#### Unfunded Mandates

OSM has determined and certifies pursuant to the Unfunded Mandates Reform Act (2 U.S.C. 1502 *et seq.*) that this rule will not impose a cost of \$100 million or more in any given year on local, state, or tribal governments or private entities.

#### List of Subjects in 30 CFR Part 936

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 20, 1998.

#### Brent Wahlquist,

Regional Director, Mid-Continent Regional Coordinating Center.

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