A. Scope

The agency seeks comments on the criteria found at § 514.1(d)(1) for the determination of a minor species or a minor use.

B. Creating Additional Statutory Authority

Should there be different standards for target animal safety and effectiveness of new animal drugs intended for use in minor species or for minor uses? Should there be different standards for human food safety for new animal drugs intended for minor species and for minor uses? If so, what should those standards be? Should the standards be the same for all minor species or uses? Why? Should products be labeled to reflect the use of different standards? If not, why not? If the act were amended to permit FDA to approve new animal drugs for a minor species or minor use under different standards, how would appropriate doses be determined and how would residue depletion and withdrawal times for food animals be determined?

On the human drug side, certain critical drugs for life-threatening and serious diseases are approved though an accelerated approval process in which followup studies are required to confirm approval (see 21 CFR part 314, subpart H). Similarly, section 522 of the act (21 U.S.C. 360l) requires and authorizes the agency to require postmarket surveillance of certain devices to protect the public health or provide safety and effectiveness data. Would sponsors and users accept conditional approvals and postmarket surveillance as a tradeoff for requiring less in the way of premarket target animal safety and effectiveness studies for new animal drugs for minor species or minor uses? Should a drug approved under such a mechanism bear labeling that reflects its conditional status?

Should the act be amended to allow FDA to accept foreign reviews or approvals of new animal drugs for minor species or for minor uses? How should Congress or FDA determine whether the reviews or approvals of a particular country or countries are acceptable as a basis for approval of uses for minor species or for minor uses.

Should the current statutory standard for new animal drug approval for drugs intended for minor species or minor uses or any alternative standard be implemented through a primary review process external to the agency? If so, how might this process be administered? Who should pay for the external reviews?

Could determinations of animal safety and effectiveness by expert panels or compendia be used to support drug approvals for minor species and minor uses? If so, what information would serve as the basis for such determinations? Should the determinations of these panels or other information be used to issue monographs or similar standards? Who would draft monographs or similar standards and why?

C. Administrative and Regulatory Changes

Should there be different standards for manufacturing of drugs for minor species or minor uses? If so, what should those standards be? Should products be labeled to reflect the use of different manufacturing standards?

Would a strategy similar to that used by the agency to facilitate drug approvals for some aquatic species be successful if extended to other minor species? That strategy includes coordination of investigational new animal drug (INAD) information collected or generated by end users. It also includes a centrally-organized and CVM-operated field education program directed at end users as potential INAD sponsors. In which species/uses would such an approach work or not work? Why?

D. Creating Incentives

Would economic incentives, such as tax breaks, grants, and periods of market or label exclusivity, encourage the pursuit of approvals or supplemental approvals for labeling modifications for minor species or minor uses? If so, what kinds of incentives would be most effective? Would different kinds of incentives be appropriate for different classes of new animal drugs, such as drugs for hobbyist-owned tropical fish as contrasted with production drugs for fish intended for human consumption?

What incentives would encourage sponsors to pursue approval of a drug for a minor species or for a minor use using data in public master files (PMF's)? Are there concerns about data in PMF's that make new animal drug sponsors reluctant to rely on such data? What are those concerns? How could they be addressed?

If producer groups or other organizations were willing to conduct or otherwise fund studies to demonstrate safety and efficacy for new animal drug approvals for minor species or minor uses, would sponsors be willing to use the data from the studies to support approvals and new or revised labeling? If not, why not?

Should a program similar to the U.S. Department of Agriculture's National Research Support Program #7 (NRSP–7), which currently funds studies for minor use therapeutic uses for food- and fiber-producing animals, be developed for wildlife and zoo animals and/or for production uses? Should the NRSP–7 program be expanded to cover such uses?

Could and should philanthropic, public interest, or other not-for-profit organizations be encouraged to fund research for the development of new animal drugs intended for use in minor species or for minor uses? If so, how, and by whom?

Are there mechanisms other than the new animal drug approval process and extralabel uses of animal and human drugs under the AMDUCA that could enhance drug availability for minor species and for minor uses?

E. Extending Existing Legal Authority

Would legislation be desirable to extend the AMDUCA to permit extralabel use of: (1) Medicated feeds or (2) reproductive hormones and implants? What are the pros and cons of approval versus extralabel use under the AMDUCA?

IV. Comments

Interested persons may, on or before September 8, 1997, submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–16340 Filed 6–18–97; 1:40 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 808

[Docket No. 96N–0249]

Applications for Exemption From Preemption of State and Local Requirements Pertaining to the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for a proposed rule that appeared in the **Federal Register** of February 19, 1997 (62 FR 7390). The comment period is being opened for 14 days to accept additional comments on the agency's proposal to grant exemptions from preemption for certain cigarette and smokeless tobacco requirements in the States of Alabama, Alaska, and Utah.

DATES: Written comments must be received or postmarked by July 7, 1997. Comments postmarked after such date will not be considered.

ADDRESSES: Submit 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: Anne M. Kirchner, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5321.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 28, 1996 (61 FR 44396), FDA published a final rule (the tobacco rule) restricting the sale and distribution of nicotine-containing cigarettes and smokeless tobacco in order to protect children and adolescents. Because FDA is regulating these products as nicotine-delivery devices under the Federal Food, Drug, and Cosmetic Act (the act), any State or local requirement that is different from, or in addition to, specific requirements for cigarettes or smokeless tobacco under the tobacco rule is preempted under section 521(a) of the act (21 U.S.C. 360k). Section 521(b) of the act provides that FDA may, upon application by a State or political subdivision, and by regulation issued after notice and opportunity for an oral hearing, exempt a State or local device requirement from Federal preemption.

In the **Federal Register** of February 19, 1997 (62 FR 7390), FDA issued a proposed rule that would grant exemption from Federal preemption for certain cigarette and smokeless tobacco requirements in the States of Alabama, Alaska, and Utah.The proposed rule would allow those States to enforce State requirements that are more stringent than FDA counterpart requirements. FDA received approximately one dozen comments to the proposal and one requested that FDA extend the comment period for 14 days.

The request stated that an extension was necessary because the comment stated that the scope of preemption under section 521(a) of the act was explained differently in the tobacco rule than it was in the proposal (62 FR 7390). In order to ensure that all interested parties have a fair opportunity to comment, FDA is extending the comment period for 14 days. Comments must be either received or postmarked by July 7, 1997 in order to be considered. The agency intends to issue a final rule as soon after the comment period closes as is practicable.

Interest persons may, on or before July 7, 1997, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–16309 Filed 6–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 870

RIN 1029–AB68

Abandoned Mine Land Reclamation Fund—Basis for Coal Weight Determination; Notice of Withdrawal

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; notice of withdrawal.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is withdrawing the proposed rule published on December 29, 1992 (57 FR 62116), regarding the determination of coal weight for calculating Abandoned Mine Land (AML) reclamation fees. That proposal was intended to allow operators who transfer run-of-mine coal but are paid on a calculated clean coal basis to also pay their AML fees on that basis. In lieu of rulemaking, OSM will recognize such transactions and allow fees to be paid on the calculated clean basis in certain circumstances, within the scope of the existing regulations. This approach will provide us greater latitude in determining the tonnage on which the first sale or transfer of ownership is based.

DATES: This notice is effective June 23, 1997.

FOR FURTHER INFORMATION CONTACT: Jim Krawchyk, Division of Compliance Management, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, PA 15220. Telephone 412–921–2676. E-mail: jkrawchy@osmre,gov.

SUPPLEMENTARY INFORMATION:

I. Background
II. Reason For Agency Action

I. Background

Section 402(a) of the Surface Mining Control and Reclamation Act of 1977 (SMCRA), 30 U.S.C. 1201 *se seq.*, requires all operators of coal mining operations subject to its provisions to pay a reclamation fee on each ton of coal produced. In December 1977 OSM first promulgated regulations to implement this provision (42 FR 62714; Sec. 13, 1977). The regulations base the fee on the actual gross weight of the coal at the first sale, use, or transfer of ownership. This regulation has been in effect basically unchanged since that time.

In 1982 (47 FR 28593; June 30, 1982) we revised the regulatory language to clarify the point in time of fee determination and to stress value and weight parameters for fee calculation purposes. We added at that time 30 CFR 870.129b) (1), (2), and (3) stating that these provisions merely restate our policy since the initial implementation of the fee collection program. The preamble to the regulations, however, did not specifically discuss these three provisions.

Of importance to OSM's decision to withdraw the proposed rule are existing sections 870.12(b)(3) (ii) and (iii) providing:

(ii) Operators selling coal on a clean coal basis shall retain records that show run-of-mine tonnage, and the basis for the clean coal transaction.

(iii) Insufficient records shall subject the operator to fees based on raw coal tonnage data.

Operators and OSM personnel now interpret these provisions as authorizing OSM to allow operators to pay reclamation fees on a clean coal tonnage basis if that is the basis of the first transaction and sale. Many small operators are paid on a clean coal basis by purchasers when they deliver their run-of-mine coals to preparation plants.