Belly wall: Any piece of the black membrane lining the belly wall that is larger than 3 cm^2.

Discoloration: Any significant discoloration larger than 5 cm^2, including naturally occurring dark pigmented spots on the skin of the light side, in fillet packs designated as skin on light side only.

Parasites:

a. *Nematodes*—Each nematode with a capsular diameter greater than 3 mm or each worm not encapsulated, greater than 1 cm in length, or each worm which is objectionable by virtue of its dark colour or any other characteristic.

b. *Other Parasites*—(to be elaborated in due course).

Annex B.—Recommended Defect Table—Quick Frozen Fillets of Flat Fish

This table and the maximum allowable number of instances of defects are based on an AQL of 6.5. The defect table is not to be applied to individual packs but to consignments in association with the appropriate Sampling Plan. Instances of defects are assigned for the indicated occurrences in one kilogramme of product.

Type of defect	One instance	Additional instance
Bones		
—fillets not designated as boneless.	A single bone greater than 5 mm in any dimension, or an agglomeration of such bones within an area of 3 cm^2.	Each additional occurrence, or an agglomeration of such bones covering an area greater than 3 cm^2.
—fillets designated as boneless.	A single bone greater than 5 mm in any dimension.	Each additional occurrence.
Blood clots	A clot greater than 5 mm in any dimension.	Each additional occurrence.
External fins	A fin or part fin 3 cm^2 or less.	Each additional occurrence and, for each fin or part fin over 3 cm^2, every additional complete 3 cm^2.
Skin (fillets designated as skinless or skin on light side only).	A piece greater than 3 cm^2 up to and including 5 cm^2.	Each additional occurrence and, for each piece over 5 cm^2, every additional complete 5 cm^2.
Belly wall (black membrane).	A piece greater than 3 cm^2 up to and including 5 cm^2.	Each additional occurrence and, for each piece greater than 5 cm^2, every additional complete 5 cm^2.
Discoloration	A significant discoloration of the flesh greater than 5 cm^2 up to and including 10 cm^2.	Each additional occurrence and, for each significant discoloration over 10 cm^2, every additional complete 5 cm^2.
Parasites	A parasite with a capsular diameter greater than 3 mm or a worm not encapsulated, greater than 1 cm in length, or a worm which is objectionable by virtue of its dark colour or any other characteristic.	Each additional occurrence.

Maximum Allowable Tolerances for Defects: A sample of 1 kg is considered defective if it contains:
(a) more than 4 instances of bone defects; or
(b) a total of more than 7 instances of defects for fillets presented as skin on; or
(c) a total of more than 8 instances of defects for fillets presented as skinless or skin on light side only.

Interested persons may, on or before January 30, 1984, 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 title of the Codex standard and 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.

Executive Order 12291 does not apply to regulations issued in accordance with the formal rulemaking provisions of the Administrative Procedure Act (5 U.S.C. 556, 557). Food standards promulgated under 21 U.S.C. 341 and 371(e) fall under this exemption. However, any comments submitted in support of establishing a U.S. standard for this food should be supported by appropriate information and data regarding impact on small business consistent with the requirements of the Regulatory Flexibility Act (Pub. L. 96–354).

Dated: November 15, 1983.

Richard J. Ronk,

Acting Director, Bureau of Foods.

[FR Doc. 83–31677 Filed 11–29–83; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Parts 201 and 330

[Docket No. 82N–0050]

Citizen Petition on the Requirement for a Pregnancy-Nursing Warning for Over-the-Counter Drugs; Notice of Availability and Opportunity for Public Comment

AGENCY: Food and Drug Administration.

ACTION: Request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on a citizen petition filed by the Public Citizen Health Research Group requesting an amendment to the pregnancy-nursing warning label requirement for over-the-counter (OTC) drugs to include all OTC drugs, whether or not they are intended for systemic absorption.

DATE: Comments by January 30, 1984.

ADDRESS: Written comments and requests for single copies of the petition to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFN–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 7, 1982 (47 FR 54750), the agency proposed that a pregnancy-nursing warning be required for all OTC drugs that are systemically absorbed. The proposed warning, "As with any drug, if you are pregnant or nursing a baby seek professional advice before using this product," was similar to a warning required by California for drugs *intended* for systemic absorption.

The final rule, published in the **Federal Register** of December 3, 1982 (47 FR 54750), was similar to the proposed rule, but clarified that the agency did not intend to include drugs absorbed in amounts so small as to have no pharmacological or toxicological significance, and that drugs that are not intended for systemic absorption need not bear the warning (47 FR 54751). For example, OTC drugs used topically or mouthwashes regulated as OTC drugs, which, because of their method of use, are not intended to be systemically absorbed, are not covered by the regulation. This approach is consistent with that of the California regulation, which, as stated above, applies only to drugs intended for systemic absorption into the human body. Upon receipt of appropriate data, however, a specific pregnancy warning may be proposed as part of the OTC drug review for any OTC drug product, including one that is not intended for systemic absorption.

The Public Citizen Health Research Group (the petitioner), 2000 P Street NW., Washington, DC 20036, has petitioned FDA under the provisions of § 10.30 *Citizen Petition* (21 CFR 10.30) to amend the requirement for the pregnancy-nursing warning label for OTC drugs in § 201.63(a) and § 330.2 (21 CFR 201.63(a) and 330.2) by extending

the labeling requirement to all drugs, whether or not they are intended for systemic absorption.

Summary of Petitioner's Views

The following narrative summarizes the information and arguments presented by the petitioner in support of its proposal. The material included in the narrative does not necessarily represent the views of the agency.

The distinction that FDA has drawn between OTC drugs intended for systemic absorption and those not intended for systemic absorption cannot be justified. Many, if not all, topically applied OTC drugs (such as creams and ointments applied to the skin) are absorbed through the skin and enter the bloodstream to some degree. Once they enter the bloodstream, these drugs have the potential to harm the fetus and the nursing infant, just like drugs that are "intended" for systemic absorption. Thus, because the purpose of the regulation is to ensure that pregnant and nursing women are aware of the harm that may result from their use of OTC drugs, all such drugs, even those not intended for systemic absorption, should be subject to the labeling requirement.

The agency stated that it did not intend to include drugs that are absorbed in insignificant amounts (47 FR 54751). However, even if a topical preparation contains only a small amount of a drug, or even if only a small amount of a topically applied drug is systemically absorbed, the concentration of drug in the blood or in breast milk may still be sufficient to harm the fetus or the nursing infant. Thus, topically applied drugs that contain even small quantities of active ingredients may cause birth defects (or developmental defects). Furthermore, the OTC pregnancy and nursing warning currently in effect applies to all drugs intended for systemic absorption and does not distinguish between products on the basis of the amount of active ingredients that they contain.

It should not be necessary to prove that a particular OTC drug that is not intended for systemic absorption is harmful to the fetus or the nursing infant in order to require that the drug bear a warning label concerning use during pregnancy and nursing. Such proof is not required for those drugs already covered by the labeling rquirement. In discussing the type of evidence necessary to establish the need for a warning label on OTC drugs that are intended for absorption, FDA stated that "athough there is at present a lack of specific evidence to show that many of these drugs cause harm to the fetus or nursing infant, the agency believes that existing evidence establishing the potential for some OTC drugs to have harmful effects on the fetus or nursing infant warrants warning pregnant and nursing women to exercise caution and seek advice from a health professional." (See 47 FR 54754.)

Absolute proof that a particular OTC drug is systemically absorbed should not be necessary to invoke the labeling requirement because, as a general rule, drugs applied to the skin or mucous membrane are systemically absorbed to some degree. Drug absorption through the skin is known to increase when the skin is inflamed or diseased, and these conditions are likely to exist when topically applied OTC drugs are being used. Thus, FDA must err on the side of caution and assume that all OTC drugs are systemically absorbed unless a manufacturer can prove otherwise.

Many OTC drugs that are not "intended" for systemic absorption are known to be systemically absorbed. Some of these drugs, when taken orally, have been associated with birth defects. In some cases, the risk of birth defects from these drugs is considered to be serious enough to warrant a specific warning on the label when the drug appears in a prescription formulation. Such drugs provide the strongest evidence that OTC drugs, even those that are not intended for systemic absorption, may pose a risk to the fetus or the nursing infant and should be required to carry the general warning concerning their use during pregnancy and while nursing. Examples of such drugs are as follows:

Hydrocortisone (cortisol) and hydrocortisone acetate are corticosteroids and constitute the primary active ingredients in several OTC topical anti-itch medications. "The Handbook for Prescribing Medications During Pregnancy" states that "chronic maternal steroid ingestion during the first trimester has been associated with approximately a 1% incidence of cleft palate in human offspring. Because of animal studies suggesting an effect on neurological and pulmonary development in fetuses exposed to steroids in utero, caution is necessary in administering such drugs to pregnant women." When used in its topical form, hydrocortisone will not be required to carry the new warning because it is not intended for systemic absorption. However, there is a possibility that hydrocortisone causes birth defects or developmental defects at the level of exposure that results from its use in an OTC cream.

Diphenhydramine hydrochloride is an antihistamine contained in a variety of prescription and OTC medications. In OTC preparations, it is used topically as an anti-itch medication for the relief of itching associated with rashes, insect bites, and other minor skin irritations. The following warning on the use of diphenhydramine appears in "The Handbook for Prescribing Medications During Pregnancy": "Because of its possible association with an increased incidence of oral clefts, diphenhydramine should not be used in the first trimester [of pregnancy] for reducing self-limited symptoms and the discomfort of allergies." Furthermore, diphenhydramine is not recommended for use by nursing mothers because it may inhibit lactation, and small amounts may be excreted in breast milk. Even though topical preparations will not be required to bear a warning, diphenhydramine is known to be systemically absorbed when topically applied, and the amount of diphenhydramine contained in OTC topical preparations is not insignificant. Absorbed quantities of topically applied diphenhydramine could equal or exceed those reached by the use of prescription capsules or OTC oral formulations of diphenhydramine, both of which will carry warnings about use during nursing and pregnancy. For example, a 1-ounce tube of a diphenhydramine cream may contain 560 milligrams (mg) of diphenhydramine hydrochloride. In contrast, prescription capsules contain 25 and 50 mg of diphenhydramine hydrochloride, and a 4-ounce bottle of an OTC cough syrup contains 330 mg of diphenhydramine hydrochloride (12.5 mg per teaspoon). A pregnant or nursing woman with a bad rash or serious case of poison ivy could easily use one-third of a 1-ounce tube of cream in one application. Even if only one-fifth of the applied substance (180 mg) was systemically absorbed, the absorbed amount (36 mg) would be greater than that contained in 2 teaspoons of cough syrup.

Estogens and progesterone, both of which are known to cause birth defects, are contained in several currently marketed hormone creams. The current detailed patient package insert for combination oral contraceptives warns that oral contraceptives should not be taken by pregnant women because they may damage the developing child. In addition, the insert warns that the developing female child whose mother has received diethylstilbestrol, an estrogen, during pregnancy has a risk of getting cancer of the vagina or cervix in her teens or young adulthood. This risk, according to the insert, is estimated to be about 1 in 1,000 exposures or less. The insert also states that "abnormalities of the urinary and sex organs have been reported in male offspring so exposed. It is possible that other estrogens such as the estrogens in oral contraceptive could have the same effect in the child if the mother takes them during pregnancy."

Identical or similar warnings are included in patient package inserts for other oral contraceptives, conjugated estrogens (including estrogen cream for vaginal use), and esterified estrogens. Patient information sheets for oral contraceptives are also required to contain a warning stating that the hormones in the drug are known to appear in breast milk, and that they may also decrease the quantity of milk produced.

Progesterone has not been well studied with respect to systemic absorption from topical application. However, FDA requires a patient package insert for progestational drugs to warn about the risk of birth defects from the use of these drugs during pregnancy.

Many other OTC drugs not "intended" for systemic absorption are known to be systemically absorbed when applied topically and can reach toxic concentrations in the blood. Because these drugs can be toxic to the user when topically applied, it is likely that they can also harm the fetus or the nursing infant when absorbed from topical preparations. Among these drugs is neomycin sulfate, an antibiotic contained in several OTC ointments. Neomycin sulfate is used to prevent infection and to aid the healing of minor cuts, burns, and abrasions. However, deafness, one of the effects of neomycin toxicity, has been reported following topical use of this drug.

Other topically applied drugs that can cause toxic effects when systematically absorbed are dibucaine, lidocaine, and tetracaine, which are local anesthetics used

in OTC topical medications for the relief of pain and itching. Because some of these drugs are contained in preparations indicated for the treatment of hemorrhoids, they are applied to the rectal area, where there is a good chance that they will come into contact with mucous membrane. The mucous membrane of the rectum permits a high degree of absorption of many substances. Consequently, systemic absorption of these products is very likely to occur when they are applied inside or near the rectum. Because pregnant women are particularly prone to developing hemorrhoids, they may well use these products.

Boric acid, salicyclic acid, and phenol are other examples of drugs that are known to be systemically absorbed and capable of producing toxic effects. Boric acid is an antiseptic contained in products used to treat hemorrhoids. Salicyclic acid is an antimicrobial ingredient contained in many OTC medications used in the treatment of athlete's foot, jock itch, acne, psoriasis, and dandruff. It is also found in wart removers. Phenol is an analgesic and antiseptic found in many OTC drug products.

Many other drugs contained in OTC topical drug products are known to be absorbed through the skin. Although not known to cause birth defects or to be toxic to the user, they are systemically absorbed and thus have the potential to harm the fetus or the nursing infant. Examples of such drugs are histamine dihydrochloride, a topical analgesic; resorcinol, a topical analgesic and keratolytic contained in such products as acne creams and a feminine itching medication; tripelennamine, an antihistamine contained in some topical analgesics; and benzoyl peroxide, an antimicrobial drug that is the chief ingredient in many anti-acne medications.

Other examples of topically applied OTC drug products are mouthwashes, gargles, throat sprays, and other oral antimicrobial drugs. The final rule requiring the pregnancy-nursing warning specifically exempted mouthwashes (47 FR 54751). However, these products, too, may be systemically absorbed, and adverse effects may result from systemic absorption.

Most of the examples that have been cited are topically applied OTC drugs. However, there are many other types of OTC drugs that are not "intended" for systemic absorption but that may be systemically absorbed and thus pose a potential danger to the fetus and the nursing infant. Many of these products are frequently not thought of as drugs, but they are drugs and are regulated as such by FDA. Examples of such drugs are dandruff shampoos, products for hair growth and hair removal, lice-killing ingredients (pediculicides), antiperspirants, and sunscreen products.

The preceeding examples are not meant to be an exhaustive review of the scientific evidence on the systemic absorption of OTC drugs that are not intended for systemic absorption. Rather, the examples are sufficient to illustrate the unscientific nature of FDA's distinction between drugs "intended" for systemic absorption and other OTC drugs.

Under section 502(a) of the Federal Food, [illegible] and Cosmetic Act, a drug is misbranded, and this cannot be sold, if its labeling is "false or misleading in any particular." Labeling is "misleading" if it fails to reveal material facts "with respect to consequences which may result from use" of the drug. FDA has determined that any systemically absorbed drug used during pregnancy or while nursing "may pose some risk to the fetus or newborn child" (47 FR 54754). Thus, this is a material fact that must be disclosed in the labeling of all drugs that are systemically absorbed, whether such absorption is intended or not. By limiting the scope of the final rule to only those drugs "intended" for systemic absorption, FDA has failed to cure the misbranding of all drugs that pose a threat to the fetus or nursing child. "For the same reasons, we believe that FDA has acted in an arbitrary and capricious manner in violation of section 10(e) of the Administrative Procedure Act, 5 U.S.C. 706."

The petitioner concludes by urging FDA to grant the petition and amend the labeling requirement to apply to all OTC drugs. The petitioner states that this amendment should include all OTC drugs that are not intended for systemic absorption but that are known to be systemically absorbed, as well as all OTC drugs that have not yet been studied, because they may be systemically absorbed. The petitioner contends that FDA must assume that all OTC drugs are capable of systemic absorption, and thus should be subject to the labeling requirements, unless a manufacturer is able to demonstrate otherwise in a particular case.

The petitioner asks that the agency respond to the petition as quickly as possible. The petitioner explains that if FDA grants the petition, and does so promptly, manufacturers of newly affected OTC drug products will have sufficient time to comply with the amended regulation by December 5, 1983, the date by which all currently affected products must meet the current labeling requirement.

The agency notes that, because of the 60-day comment period provided for in this document and the time that will be needed to evaluate the comments, it will be unable to reach a final decision on the merits of the petitioner's request before the December 5, 1983 effective date for implementation of the pregnancy-nursing warning requirement. In an interim response the agency notified the petitioner of this fact. The agency will, however, take final action on the petition as soon as possible.

Request for Comments

The petitioner raises issues that need to be addressed before FDA can make a final decision on the feasibility of amending the requirement for the pregnancy-nursing warning. Therefore, in accordance with § 10.30(h)(3) (21 CFR 10.30(h)(3)), the Commissioner of Food and Drugs is seeking public comments on the following questions before reaching any decision on the petition.

1. Does the current requirement, which exempts from the pregnancy-nursing warning label OTC drugs not intended for systemic absorption, adequately protect the fetus and the nursing child, even though it is known that certain of these drugs can be systemically absorbed to some degree when applied topically?

2. Under what circumstances, if any, should FDA request a pregnancy-nursing warning label for OTC drugs not intended for systemic absorption? For example:

Should FDA require a warning label if it knows that a topical OTC drug is systemically absorbed?

Should FDA require a warning label on the assumption that all drugs are capable of systemic absorption even though they have not yet been studied and there is no evidence that the OTC drug is systemically absorbed?

3. What data are available on the active ingredients in OTC drugs that are not intended for systemic absorption and that have been associated with birth defects (e.g., estrogens, hydorcortisone)?

4. What data are available on the amount of active ingredients in OTC drugs that are not intended for systemic absorption, but that are absorbed into the body?

The complete petition is on public display between 9 a.m. and 4 p.m., Monday through Friday, in the Dockets Management Branch. Requests for single copies of the petition may be submitted to the Dockets Management Branch and should be identified with the docket number found in brackets in the heading of this document.

Interested perons may, on or before January 30, 1984 submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane Rockville, MD 20857, written comments regarding this petition. Three 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 and may be accompanied by a supporting memorandum or brief. The petition and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

If, after reviewing the comments and other information available to him, the Commissioner concludes that the petition has sufficient merit, he will

propose to amend the regulations requiring the pregnancy-nursing warning for OTC drugs to include all OTC drugs that are systemically absorbed. The Commissioner issues this notice under section 701(a) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 10.30.

Dated: November 23, 1983.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 83-31959 Filed 11-29-83; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

Consideration of Amendments to the Kentucky Permanent Program Under the Surface Mining Control and Reclamation Act of 1977

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

ACTION: Reopening of public comment period.

SUMMARY: OSM is reopening the period for review and comment on certain amendments submitted by the Commonwealth of Kentucky to its program for the regulation of surface coal mining and reclamation in the State published at 47 FR 31890, July 23, 1982, and 47 FR 39536, Sept. 8, 1982). The amendments relate to (1) operations involving the crushing, screening or loading of coal, and (2) auger mining. OSM is reopening the comment period to allow the public sufficient time to consider and comment on the proposed amendments.

DATES: Written comments, data or other relevant information must be received on or before 4:00 p.m. December 30, 1983 to be considered.

ADDRESSES: Comments should be sent or hand-delivered to: W. H. Tipton, Director, Kentucky Field Office, Office of Surface Mining, 340 Legion Drive, Suite 28, Lexington, Kentucky 40504.

FOR FURTHER INFORMATION CONTACT: W. H. Tipton, Director, Kentucky Field Office, Office of Surface Mining, 340 Legion Drive, Suite 28, Lexington, Kentucky 40504. Telephone: (606) 233-7327.

SUPPLEMENTARY INFORMATION: On May 28, 1982, OSM received, pursuant to the 30 CFR 732.17 State program amendment procedures, certain revisions to the State rules and laws. On July 23, 1982, OSM published a notice in the **Federal Register** announcing receipt of the amendments to the Kentucky program and inviting public comment thereon (47 FR 31890-31896). The public comment period ended August 23, 1982. A public hearing was held August 12, 1982. OSM published a second notice in the **Federal Register** on September 8, 1982, announcing receipt of provisions to satisfy conditions (k) and (l), and inviting public comment on whether the proposed amendments corrected these deficiencies (47 FR 39536-39537). The public comment period ended October 8, 1982. A public hearing scheduled September 22, 1982, was not held because no one expressed a desire to present testimony.

On January 4, 1983 (48 FR 245-252), OSM published a notice in the **Federal Register** which (1) removed and amended certain conditions; (2) approved certain other program amendments; (3) deferred Secretarial action on the following proposed Kentucky rule revisions: 405 KAR 7:020 Section 1(86), 8:050 Section 2, 16:020 Section 4 and 16:190 Section 2(2); (4) deferred Secretarial action on the following proposed Kentucky statutory revisions: KRS 350.060 Sections 5(21) and 5(22), 350.093(2), and 350.062(9), contained in Senate Bill 218; (5) approved certain clarifications to the Kentucky program contained in a letter from the State, dated June 18, 1982; (6) deferred Secretarial action on the clarification in the June 18, 1982, letter relating to incidental boundary revisions; and (7) deferred Secretarial action on whether the material submitted by Kentucky satisfied condition (1).

On May 13, 1983 (48 FR 21574-21579), OSM published a notice in the **Federal Register** which (1) removed condition (1); (2) approved amendments to KRS 350.062(9) and 350.093(2), and 405 KAR 16:020 Section 4; and 3) created two new conditions of approval, relating to the deferral of contemporaneous reclamation (KRS 350.093(2) and 405 KAR 16:020 Section 4) and the definition of "principal shareholder" (KRS 350.060 Section 5(g) and 405 KAR 7:020 Section 1(86)).

On April 28, 1983 (48 FR 19314-19322), OSM published a notice in the **Federal Register**, effective May 27, 1983, revising its rules for conducting auger mining. On May 5, 1983 (48 FR 20392-20402), OSM published a notice in the **Federal Register**, effective June 6, 1983, amending its rules applicable to support facilities and coal preparation plants. These OSM rule revisions relate to certain of the items listed above on which the Secretary deferred action in the January 4, 1983 **Federal Register** notice as follows: (1) 405 KAR 8:050 Section 2 and 16:190 Section 2(2), and KRS 350.060 Section 5(21) (augering), and (2) KRS 350.060 Section 5(22) (support facilities and coal preparation plants).

In the **Federal Register** dated June 13, 1983, OSM reopened the comment period to allow the public sufficient time to review and comment on the above Kentucky amendments (48 FR 27101). The public comment period closed June 28, 1983.

On July 11, 1983 (48 FR 31668-31669), OSM published a notice in the **Federal Register** reopening the comment period to allow the public additional time to review and comment on the above Kentucky amendments. The public comment period closed July 26, 1983.

On September 16, 1983 (48 FR 41720-41735), OSM published a notice in the **Federal Register** amending its rules on remining.

On October 31, 1983, OSM received additional material from Kentucky, responding to four issues raised by OSM regarding the Kentucky amendments. This material consisted of an explanatory letter and a legal opinion, dated October 26, 1983, addressing crusher and loader jurisdiction and augering on previously mined areas. OSM also received a number of emergency regulations including revisions to 405 KAR 16:190 and 18:190, regarding requirements for adequate drainage on backfilled areas and criteria for determining reasonably available spoil to backfill highwalls to the extent practical and feasible.

OSM is reopening the comment period for an additional 30 days to allow the public sufficient time to review and comment on the above Kentucky amendments in light of OSM's September 16, 1983, rule revisions and the material submitted by the State on October 31, 1983. If the amendments are approved, they will become part of the Kentucky program.

This announcement is made in keeping with OSM's commitment to public participation as a vital component in fulfilling the purposes of SMCRA.

Dated: November 22, 1983.

William B. Schmidt,

Assistant Director, Program Operations and Inspection.

[FR Doc. 83-31939 Filed 11-29-83; 8:45 am]

BILLING CODE 4310-05-M