PART 33—APPLICATION FOR SALE, LEASE, OR OTHER DISPOSITION, MERGER OR CONSOLIDATION OF FACILITIES, OR FOR PURCHASE OR ACQUISITION OF SECURITIES OF A PUBLIC UTILITY

1. The authority citation for part 33 is revised to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

2. In § 33.2, paragraphs (b), (d), (g), (h), (i), and (n) are removed, paragraph (c) is redesignated as paragraph (b), paragraphs (e), (f), and (j) are redesignated as paragraphs (c) (d), and (e), paragraphs (k), (l), and (m) are redesiganted as paragraphs (f), (g), and (h), and paragraphs(o), (p), (q), and (r) are redesignated as paragraphs (i), (j), (k), and (l), and newly redesigned paragraph (c) is revised to read as follows:

§ 33.2 Contents of application; filing fee.

* * * * *

(c) Designation of the territories served, by counties and States.

* * * * *

3. In § 33.3, Exhibits A, B, D, and E are removed, Exhibit C is redesignated as Exhibit A, Exhibits F through M, are redesignated as Exhibits B through I, respectively, the final "Note" paragraph is removed, and the introductory text is revised to read as follows:

§ 33.3 Required exhibits.

There shall be filed with the application as part thereof one certified copy and five uncertified copies plus one for each State affected of Exhibits B, C, D, E, F, G, H, and I, described as follows:

* * * * *

PART 35—FILING OF RATE SCHEDULES

4. The authority citation for part 35 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

§ 35.13 [Amended]

5. In § 35.13, paragraph (d)(6) is removed, paragraph (d)(7) is redesignated as paragraph (d)(6), paragraph (h)(7)(iv) is removed, and paragraphs (h)(7)(v) and (h)(7)(vi) are redesignated as paragraphs (h)(7)(iv) and (h)(7)(v).

6. In § 35.19a, paragraph (b) is revised to read as follows:

§ 35.19a Refund requirements under suspension orders.

* * * * *

(b) *Reports.* Any public utility whose proposed inreased rates or charges were suspended and have gone into effect pending final order of the Commission pursuant to section 205(e) of the Federal Power Act shall keep accurate account of all amounts received under the increased rates or charges which became effective after the suspension period, for each billing period, specifying by whom and in whose behalf such amounts are paid.

§ 35.22 [Removed]

7. Section 35.22 is removed.

§§ 35.23 Through 35.31 Redesignated as §§35.22 Through 35.30.

8. Sections 35.23 through 35.31 are redesignated as §§ 35.22 through 35.30.

PART 290—COLLECTION OF COST OF SERVICE INFORMATION UNDER SECTION 133 OF THE PUBLIC UTILITY REGULATORY POLICIES ACT OF 1978

9. The authority citation for part 290 is revised to read as follows:

Authority: 16 U.S.C. 791a–828c, 2601–2645 (1988); 42 U.S.C. 7101–7352 (1988).

10. Section 290.102 is revised to read as follows:

§290.102 Information gathering and filing.

All non-exempt public utilities shall file the data required by section 133(a) of the Public Utility Regulatory Policies Act of 1978 with their state regulatory authorities. All non-exempt non-public utilities shall make these data publicly available.

§§ 290.103 through 290.701 [Removed]

11. §§290.103 through 290.701 are removed.

[FR Doc. 92–12818 Filed 6–1–92; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 334

[Docket No. 78N–036L]

RIN 0905–AA06

Laxative Drug Products for Over-The-Counter Human Use; Tentative Final Monograph; Reopening of Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking; reopening of administrative record.

SUMMARY: The Food and Drug Administration (FDA) is reopening the administrative record for the rulemaking for over-the-counter (OTC) laxative drug products to include data on the stimulant laxative active ingredient derived from senna and data on the combination of psyllium and bran laxative active ingredients. This action is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by August 3, 1992.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 21, 1975 (40 FR 12902), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC laxative, antidiarrheal, emetic, and antiemetic drug products together with the recommendations of the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. The agency's proposed regulation, in the form of a tentative final monograph, for OTC laxative drug products was published in the Federal Register of January 15, 1985 (50 FR 2124).

In the advance notice of proposed rulemaking, the Panel classified senna preparations as Category I (safe and effective) stimulant laxatives and recommended dosages for the various senna preparations, i.e., senna leaf powder, senna fluidextract, senna fruit extract, senna syrup, sennosides A and B crystalline, and senna pod concentrate (40 FR 12902 at 12909).

In the tentative final monograph (50 FR 2124 at 2141), the agency stated that the available data show that the active constituents in the various senna preparations are sennosides A and B. In many submissions to the Panel, the dosage of various senna preparations was standardized to sennosides A and B only. Because the active constituent in the senna compounds is sennosides A

and B, the agency proposed a dosage only for sennosides A and B in the tentative final monograph. The allowable sources of sennosides A and B, i.e., senna leaf powder, senna fluidextract, senna pod concentrate, senna fruit extract, senna syrup, or sennosides A and B crystalline, were listed in the tentative final monograph, but specific dosages for each individual senna preparation were not provided. The agency also stated that manufacturers may market their products in the formulation of their choice, using any of the allowable sources of senna, provided that the equivalent dosage conforms to the dosages for sennosides A and B set out in the tentative final monograph (50 FR 2124 at 2141, 2152, and 2156).

On July 10, 1991, the agency received a citizen petition (Ref. 1) requesting that the stimulant laxative active ingredient from the senna plant be listed as "sennosides" and not be limited to "sennosides A and B." The request was based on scientific studies isolating and identifying the various anthracene derivatives from the leaves and pods of senna. The petition stated that sennosides A, B, C, and D, and rhein and aloe-emodin in the free and glycoside form may be present. The petition added that Khafagy, S. M. et al. (Ref. 2) confirmed the presence of the different sennosides in a thin layer chromatographic-spectroscopic method developed to separate and quantitate sennosides A, B, C, and D in senna leaves, pods, and various senna-containing pharmaceutical preparations. The petition noted that the British Pharmacopoeia 1988 (Ref. 3) identifies sennosides A, B, C, and D, and rhein–8–glucoside as the hydroxyanthracene glucosides present in senna leaves and fruit. In addition, the United States Pharmacopeia XXII (Ref. 4) refers to the "partially purified natural complex of anthraquinone glucosides found in senna" collectively as sennosides.

According to the petition, several studies have investigated the pharmacologic effect of various anthracene derivatives in senna. Marvola, M. et al. (Ref. 5) compared the laxative effect of commercial sennosides and senna extracts of varying purity. They found the pure sennoside to be a less potent laxative than the sennoside extracts, but with a corresponding lower acute toxicity, indicating the presence of other similar compounds which have a laxative potency that is either higher than sennosides A and B alone, or that is synergistic with these sennosides.

The petition contended that sennosides A and B are not the only active ingredients responsible for laxation, and product labeling based on sennosides A and B as the only active ingredients is inaccurate and misleading. The petition, therefore, requested that the stimulant laxative active ingredient derived from senna be listed as "sennosides" and that all dosage schedules be based on the amount of total sennosides contained in the drug product.

In the tentative final monograph, the agency agreed with the Panel's Category I classification of both psyllium and bran as bulk-forming laxative active ingredients (50 FR 2124 at 2149). The agency also stated that both the "General Guidelines for OTC Drug Combination Products" (Ref. 6) and the regulations in § 330.10(a)(4)(iv) provide that an OTC drug product may combine two or more safe and effective active ingredients provided the product meets the combination policy in all respects (50 FR 2124 at 2145). The agency noted that if a manufacturer could show, with supportive data, that a laxative combination meets the general guidelines for OTC combination drug products, the agency would not object to the product containing two or more Category I laxative ingredients (50 FR 2145).

On December 18, 1990, the agency received a citizen petition (Ref. 7) requesting that the tentative final monograph for OTC laxative drug products be amended to allow the combination in a single product of two generally recognized safe and effective bulk-forming active ingredients, psyllium and bran, used within monograph-specified dosage limits. The request cited § 330.10(a)(4)(iv), which states that an OTC drug may combine two (or more) safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect, the combination does not decrease the safety or effectiveness of either individual ingredient, and the combination provides rational concurrent therapy for a significant proportion of the target population.

The petition stated that psyllium and bran each were proposed as generally recognized as safe and effective bulk-forming laxative ingredients in the tentative final monograph (50 FR 2124 at 2152). When formulated together as a combination product, each contributes to the claimed laxation effect, and neither ingredient detracts from the safety and/or effectiveness of the other. The petition contended that the combination of psyllium and bran provides rational concurrent therapy on the basis of consumer acceptance as well as quality of product formulation. The petition added that in order to achieve a form of a psyllium-based laxative product suitable for teaspoon dosing, it is necessary to use an ingredient (usually inactive) as an extender, typically in the form of a polysaccharide, such as sucrose or maltodextrin. Substitution of bran for sucrose or maltodextrin offers three advantages: (1) Bran is compatible with psyllium in terms of physical characteristics (e.g., color, texture) and chemical characteristics (e.g., product stability); (2) bran does not contribute significant caloric value to the product and obviates the need for an additional extender; and (3) at the therapeutic levels proposed in 21 CFR 334.31, bran would contribute towards the overall laxation effect.

FDA has carefully considered these requests and believes that it would be appropriate to reopen the administrative record for the rulemaking for OTC laxative drug products to include the information included in these petitions on the stimulant laxative active ingredient derived from senna and on the psyllium-bran combination drug product. The petition on sennosides contains new evidence demonstrating that sennosides A and B are not the only active principles and that dosage schedules based upon the amount of total sennosides in the product are more accurate. The petition on the psyllium-bran combination drug product provides good reasons why such a product increases consumer acceptance and improves the quality of product formulation. (See discussion above.) Therefore, the agency considers that good cause exists, as stated in § 330.10(a)(7)(v), to consider at this time: (1) listing the stimulant laxative active ingredient as "sennosides" instead of "sennosides A and B" as was proposed in § 334.18(h); and (2) the possible monograph status of a psyllium-bran

combination laxative drug product. The agency is currently developing the final monograph. The agency believes that it is appropriate to resolve these issues before the final monograph is published.

At this time, the agency is unaware of any OTC laxative drug product that contains psyllium and bran as active ingredients in combination on the market in the United States. Therefore, unless and until the agency determines that the combination of psyllium and bran as active ingredients in OTC laxative drug products is Category I and states its position in the **Federal Register**, the marketing of such a combination is prohibited in the absence of an approved new drug application.

Interested persons may on or before August 3, 1992, submit to the Dockets Management Branch (address above) written comments regarding the stimulant laxative active ingredient derived from senna and the ingredients psyllium and bran used in combination in laxative drug products. At this time, comments should not be submitted on any other laxative drug product. 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. Comments received may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

References

(1) Comment No. CP11, Docket No. 78N–036L, Dockets Management Branch.

(2) Khafagy, S. M. et al., "Estimation of Sennosides A, B, C, and D in Senna Leaves, Pods and Formulations," *Planta Medica*, 21:304–309, 1972.

(3) "British Pharmacopoeia," The British Pharmacopoeia Commission, vol. 1, p. 501, 1988.

(4) "The United States Pharmacopeia XXII—The National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 1246, 1990.

(5) Marvola, M. et al., "The Effect of Raw Material Purity on the Acute Toxicity and Laxative Effect of Sennosides," *Journal of Pharmacy and Pharmacology*, 33:108–109, 1981.

(6) FDA, "General Guidelines for OTC Drug Combination Products, September, 1978," Docket No. 78D–0322, Dockets Management Branch.

(7) Comment No. CP9, Docket No. 78N–036L, Dockets Management Branch.

Dated: May 27, 1992.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 92–12785 Filed 6–1–92; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[PS–260–82]

RIN 1545–AE26

Definition of Passive Investment Income; Hearing Cancellation

AGENCY: Internal Revenue Service, Treasury.

ACTION: Cancellation of notice of public hearing on proposed regulations.

SUMAMRY: This document provides notice of cancellation of public hearing on proposed Income Tax Regulations that relate to the definition of passive investment income.

DATES: The public hearing originally scheduled for Thursday, June 4, 1992, beginning at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Carol Savage of the Regulations Unit, Assistant Chief Counsel (Corporate), 202–377–9236 or 202–566–3935 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations under section 1362 of the Internal Revenue Code of 1986. A notice appearing in the **Federal Register** for Friday, April 17, 1992 (57 FR 13680), announced that the public hearing on the proposed regulations would be held on Thursday, June 4, 1992, beginning at 10 a.m., in the Commissioner's Conference Room, room 3313, Internal Revenue Service Building, 1111 Constitution Avenue, NW., Washington, DC.

The public hearing scheduled for Thursday, June 4, 1992, has been cancelled.

Dale D. Goode,

Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 92–12763 Filed 6–1–92; 8:45 am]

BILLING CODE 4830–01–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

Ohio Regulatory Program; Revision of Administrative Rule

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

ACTION: Proposed rule; reopening of public comment period

SUMMARY: OSM is reopening the public comment period for Revised Program Amendment Number 51 to the Ohio permanent regulatory program (hereinafter referred to as the Ohio program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Ohio has proposed additional revisions to the State's earlier submission of Program Amendment Number 51. Together, Program Amendments Number 51 and Revised 51 are intended to authorize the use of excess spoil from a valid, permitted coal mining operation for the reclamation of an adjacent unreclaimed area.

This notice sets forth the times and locations that the Ohio program and proposed amendments to that program will be available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendments, and the procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received on or before 4 p.m. on June 17, 1992. If requested, a public hearing on the proposed amendments will be held at 1 p.m. on June 12, 1992. Requests to present oral testimony at the hearing must be received on or before 4 p.m. on June 8, 1992.

ADDRESSES: Written comments and requests to testify at the hearing should be mailed or hand-delivered to Mr. Richard J. Seibel, Director, Columbus Field Office, at the address listed below. Copies of the Ohio program, the proposed amendments, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requeste may receive, free of charge, one copy of the proposed amendments by contacting OSM's Columbus Field Office.

Office of Surface Mining Reclamation and Enforcement, Columbus Field Office, 2242 South Hamilton Road, room 202, Columbus, Ohio 43232, Telephone: (614) 866–0578

Ohio Department of Natural Resources, Division of Reclamation, 1855 Fountain Square Court, Building H–3, Columbus, Ohio 43224, Telephone: (614) 265–6675

FOR FURTHER INFORMATION CONTACT: Mr. Richard J. Seibel, Director, Columbus Field Office, (614) 866–0578.

SUPPLEMENTARY INFORMATION:

I. Background

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. Information on the