

decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 97-ASO-25." The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. All comments submitted will be available for examination in the Office of the Assistant Chief Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, Airspace Branch, ASO-520, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11-2A which describes the application procedure.

The Proposal

The FAA is considering an amendment to 14 CFR part 71 to amend the Class E airspace areas at Owensboro, KY. A VOR RWY 5 SIAP has been developed for Owensboro-Daviess County Airport. Additional controlled airspace is needed to accommodate the SIAP and for IFR operations at the airport. This proposal would provide a southwest extension to the existing Class D surface area and increase the radius of the Class E airspace that extends upward from 700 feet above the surface of the earth. Class E airspace areas designated as an extension to a Class D or Class E surface area, and Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraphs

6004 and 6005, respectively, of FAA Order 7400.9E dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6004 Class E airspace areas designated as an extension to a Class D or Class E surface area.

* * * * *

ASO KY E4 Owensboro, KY [Revised]

Owensboro-Daviess County Airport, KY (Lat. 37°44'25" N, long. 87°10'23" W) Owensboro VOR/DME

(Lat. 37°44'37" N, long. 87°09'57" W)

That airspace extending upward from the surface within 3 miles each side of Owensboro VOR/DME 351°, 177°, and 223° radials, extending from the 4.1-mile radius of Owensboro-Daviess County Airport to 7 miles north, south and southwest of the Owensboro VOR/DME. This Class E airspace area is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

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Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

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ASO KY E5 Owensboro, KY [Revised]

Owensboro-Daviess County Airport, KY (Lat. 37°44'25" N, long. 87°10'23" W)

That airspace extending upward from 700 feet or more above the surface within a 7.2-mile radius of Owensboro-Daviess County Airport.

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Issued in College Park, Georgia, on November 7, 1997.

Nancy B. Shelton,
Acting Manager, Air Traffic Division,
Southern Region.

[FR Doc. 97-30356 Filed 11-18-97; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 333, 347, and 348

[Docket Nos. 80N-0476, 78N-0301, 78N-0021, and 75N-0183]

RIN 0910-AA01

Antifungal Drug Products for Over-the-Counter Human Use; External Analgesic Drug Products for Over-the-Counter Human Use; Skin Protectant Drug Products for Over-the-Counter Human Use; and Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Reopening of Administrative Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of administrative records.

SUMMARY: The Food and Drug Administration (FDA) is announcing the reopening of the administrative records for four rulemakings to include safety and effectiveness data on over-the-counter (OTC) vaginal douche drug product ingredients that were previously considered in the advance

notice of proposed rulemaking for OTC vaginal drug products. The agency is reopening the following rulemakings for consideration of data on vaginal douche drug products: (1) Antifungal drug products, (2) OTC external analgesic drug products (3) OTC skin protectant drug products and (4) OTC topical antimicrobial drug products. This action is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written comments by February 17, 1998.

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: Helen Cothran, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 13, 1983 (48 FR 46694), FDA published under 21 CFR 330.10(a)(6), an advance notice of proposed rulemaking to establish a monograph for OTC vaginal drug products, together with the recommendations of the Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in OTC vaginal drug products. In its report, the Panel recommended Category I (i.e., safe and effective) status for 1 to 3 percent potassium sorbate and 0.15 to 0.3 percent povidone-iodine as a douche for the relief of minor vaginal itching, irritation, and soreness (48 FR 46694 at 46704 to 46706). The Panel also recommended the following ingredients as Category I in a douche formulation to remove vaginal discharge and vaginal secretions, for a mild detergent action, and to thin out vaginal mucus discharge: 0.002 percent dioctyl sodium sulfosuccinate (docusate sodium), 0.0176 percent nonoxynol 9, 0.088 percent octoxynol 9, and 0.01 to 0.02 percent sodium lauryl sulfate (48 FR 46706 to 46707). In the preamble to the Panel's report (48 FR 46694 to 46695), the agency did not allow the marketing of potassium sorbate for relief of minor vaginal irritation because it was considered a new drug (had not been marketed for a material time and extent).

In the **Federal Register** of February 3, 1994 (59 FR 5226), the agency issued a notice to withdraw the advance notice

of proposed rulemaking of October 13, 1983. This action was taken in part because the agency determined that some of the Panel's recommended labeling indications related to cosmetic claims and not drug claims. The agency also stated that the intended use of a product will be considered in determining whether it is a cosmetic, a drug, or both (59 FR 5226 at 5231). In addition, recommended labeling indications and ingredients used for minor irritation, itching, or soreness are not unique to the vaginal area and are already being considered in other OTC drug rulemakings (e.g., antifungal, antimicrobial, and external analgesic). Therefore, the agency stated that those ingredients and claims would be considered in those other rulemakings, as appropriate.

II. Recent Developments

In the **Federal Register** of March 27, 1997 (62 FR 14683), the agency announced that its Nonprescription Drugs Advisory Committee (NDAC) would hold a public meeting on April 15, 1997, to discuss a possible association between vaginal douching and adverse consequences. The notice stated that FDA is aware of a number of case-control epidemiologic studies in the literature that suggest a possible association between vaginal douching and several conditions, such as pelvic inflammatory disease, ectopic pregnancy, and cervical cancer (Ref. 1). At the April 15, 1997, meeting, NDAC members were joined by representatives from two other FDA advisory committees, Reproductive Health Drugs and Anti-infective Drugs, as well as representatives from the Center for Food Safety and Applied Nutrition and the Center for Devices and Radiological Health. The Committees discussed issues relating to behavioral, epidemiological, and microbiological aspects of vaginal douching. Committee members felt that there was a suggestive association between vaginal douching and ectopic pregnancy and pelvic inflammatory disease, but that more data and further research were needed to support such an association. Some members stated that a possible association between douching and tubal infertility also needed more investigation. The Committees did not find any evidence of a relationship between vaginal douching and cervical carcinoma. Some members expressed concern that certain individuals who douche, e.g., those with sexually transmitted diseases or multiple sexual partners, may be at increased risk for ectopic pregnancy, tubal disease, or tubal infertility. The Committees were

also concerned about the risks and benefits/efficacy of vaginal douche products. The Committee members stressed that labeling for these products should be easy to read and understand, and should provide consistent information across the broad product class. The Committees encouraged the use of educational programs for both consumers and health care providers as a way to expand the public's knowledge about use of these products (Ref. 2).

III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from D. Bowen, FDA, to R.W. Soller, Nonprescription Drug Manufacturers Association, coded LET 105, Docket No. 75N-0183, Dockets Management Branch.
2. Comment No. TR1, Docket No. 80N-0476, Dockets Management Branch.

IV. Reopening of the Administrative Records

Because the issues concerning the safety of vaginal douching also have an impact on the agency's review of the safety and effectiveness of all OTC vaginal douche drug products, the agency is reopening the administrative records for the rulemakings for OTC antifungal drug products (Docket No. 80N-0476), (2) OTC external analgesic drug products (Docket No. 78N-0301), (3) OTC skin protectant drug products (Docket No. 78N-0021), and (4) OTC topical antimicrobial drug products (Docket No. 75N-0183). This action is to specifically allow for submission of data on the issues raised at the April 15, 1997, meeting. The agency also requests safety and effectiveness data on the vaginal douche drug product ingredients that were discussed at that meeting.

Interested persons may submit comments on OTC vaginal douche drug products to the applicable docket number(s) based on the ingredient's labeling claim(s), intended use, or mechanism/mode of action. For example, data on povidone-iodine for the relief of minor vaginal itching and irritation may be submitted to the external analgesic rulemaking, but if relief of itching is due to an antifungal effect, i.e., killing the fungus, data should be submitted to the antifungal rulemaking. Likewise, if data support the use of nonoxynol 9 for the relief of minor vaginal itching and irritation because of an antimicrobial action, data should be submitted to the antimicrobial rulemaking. Interested

persons should determine the appropriate rulemaking to which data should be submitted. Comments on other vaginal drug products or issues should not be submitted at this time.

Submit written comments on or before February 17, 1998 to the Dockets Management Branch (address above). Three copies of any comments are to be submitted, except that individuals may submit one copy. If comments could be submitted to several dockets, they may be submitted to one docket and cross-referenced in the other docket(s). All comments are to be identified with the appropriate docket number(s) found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-30410 Filed 11-18-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 918

[SPATS No. LA-017-FOR]

Louisiana Regulatory Program

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

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: OSM is announcing receipt of a proposed amendment to the Louisiana regulatory program (hereinafter the "Louisiana program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of revisions to and/or additions of regulations pertaining to definitions, request for hearing, permitting requirements, small operator assistance program, bond release requirements, performance standards, and enforcement procedures/civil penalties. The amendment is intended to revise the Louisiana program to be consistent with the corresponding Federal regulations.

This document sets forth the times and locations that the Louisiana program and proposed amendment to that program are available for public

inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received by 4:00 p.m., c.s.t., December 19, 1997. If requested, a public hearing on the proposed amendment will be held on December 15, 1997. Requests to speak at the hearing must be received by 4:00 p.m., c.s.t. on December 4, 1997.

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

Copies of the Louisiana program, the proposed amendment, a listing of any scheduled public hearings, 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.

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.

Department of Natural Resources, Office of Conservation, Injection and Mining Division, 625 N. 4th Street, P.O. Box 94275, Baton Rouge, LA 70804, Telephone: (504) 342-5540.

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

SUPPLEMENTARY INFORMATION:

I. Background on the Louisiana Program

On October 10, 1980, the Secretary of the Interior conditionally approved the Louisiana program. General background information on the Louisiana program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Louisiana program can be found in the October 10, 1980, **Federal Register** (45 FR 67340). Subsequent actions concerning the Louisiana program and program amendments can be found at 30 CFR 918.15 and 918.16.

II. Description of the Proposed Amendment

By letter dated October 24, 1997 (Administrative Record No. LA-362), Louisiana submitted a proposed amendment to its program pursuant to

SMCRA. Louisiana submitted the proposed amendment in response to a June 17, 1997, letter (Administrative Record No. LA-361) that OSM sent to Louisiana in accordance with 30 CFR 732.17(c). Louisiana proposes to amend the Louisiana Surface Mining Regulations. The full text of the proposed program amendment submitted by Louisiana is available for public inspection at the locations listed above under **ADDRESSES**. A brief discussion of the proposed amendment is presented below.

A. Section 105. Definitions

1. Louisiana proposes to revise its definition for "other treatment facilities."
2. Louisiana proposes to add a definition for "previously mined area."
3. Louisiana proposes to add a definition for "qualified laboratory."

B. Section 2537. Cross-Sections, Maps and Plans

Louisiana proposes to delete paragraph 2537.11. that requires cross-sections, maps and plans in the permit applications to show sufficient slope measurements to adequately represent the existing land surface configuration of the proposed permit area.

C. Section 2725. Reclamation Plan: Ponds, Impoundments, Banks, Dams and Embankments

1. Louisiana proposes to revise paragraph 2725.A. by adding "siltation structure" to the types of ponds, impoundments, banks, dams and embankments requiring a general reclamation plan, and by adding a provision that requires each application to include a detailed reclamation plan for each proposed containment structure.

2. At paragraph 2725.A.2., Louisiana proposes to delete the existing language and to replace it with language that adds specific references to the U.S. Department of Agriculture, Soil Conservation Service Technical Release No. 60 criteria for dam classification and requires compliance with this technical release if structures meet or exceed the size or other criteria of the Mine Safety and Health Administration.

3. Louisiana proposes to revise paragraph 2725.A.3. to refer to structures that are not included in paragraph 2725.A.2.

4. At paragraph 2725.A.3.a., Louisiana proposes to require qualified, registered, professional engineers to certify all coal processing waste dams and embankments covered by sections 5375 through 5395.