owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent ice accumulation on the airplane leading edges, which could result in reduced controllability of the airplane, accomplish the following:

Modification

(a) Within 1 year after the effective date of this AD, replace the flight deck pneumatic de-icing boot pressure indicator switch with a switch that activates the flight deck indicator light at 15 pounds per square inch gage, in accordance with a method approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(c) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on July 15, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–18733 Filed 7–21–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

[Docket No. 99N–1819]

RIN 0910–AA01

Topical Antifungal Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would amend the final monograph for over-the-counter (OTC) topical antifungal drug products. The amendment makes a minor change in the indications for these drug products. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written comments by October 20, 1999; written comments on the agency's economic impact determination by October 20, 1999. See section IV of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 23, 1993 (58 FR 49890), FDA published a final monograph for OTC topical antifungal drug products in part 333 (21 CFR part 333), subpart C. That monograph includes labeling in § 333.250. Section 333.250(b)(1) contains the following introductory language for the indications statement: (Select one of the following: ''Treats,'' ''For the treatment of,'' ''For effective treatment of,'' ''Cures,'' ''For the cure of,'' ''Clears up,'' or ''Proven clinically effective in the treatment of''). Section 333.250(b)(2) contains similar language for products labeled for the prevention of athlete's foot.

II. The Panel's Recommendations

The Advisory Review Panel on OTC Antimicrobial (II) Drug Products (the Panel) recommended the above labeling in its report on OTC topical antifungal drug products (47 FR 12480 at 12511, March 23, 1982). The Panel mentioned that there are several less common skin conditions that may affect the feet and the groin, cause symptoms that mimic athlete's foot and jock itch, and may be misdiagnosed as athlete's foot or jock itch. The Panel discussed common examples of such conditions: Candidiasis (a yeast infection), allergic contact dermatitis, bacterial infection of the feet (e.g., erythrasma), psoriasis, and hyperhidrosis (excessive perspiring) that may be associated with maceration of the skin and an inflammatory eruption known as dyshidrotic eczema (47 FR 12480 at 12487). While the Panel discussed these conditions, it did not address appropriate treatment or consequences of misdiagnosis of any of these conditions.

III. The Agency's Tentative Conclusions and Proposal

The agency recognizes that topical antifungal drug products will not cure or treat all conditions commonly thought by consumers to be athlete's foot or jock itch. Also, some of these conditions may have other etiologies. In addition to the conditions discussed by the Panel, consumers may erroneously consider a number of other conditions to be athlete's foot or jock itch. These include: Atopic dermatitis, irritant dermatitis, inverse pityriasis, scabies, and pediculosis pubis. All of these misdiagnosed conditions cannot be treated or cured by a topical antifungal drug product.

Because consumers self select OTC topical antifungal drug products and do not diagnose, the agency believes that the labeling should be revised to more accurately inform them what they can expect from using these products. Therefore, the agency is proposing that the word ''most'' be inserted in the allowed indications statements between the introductory phrase and the name of the condition(s) for which the product is to be used. This approach is consistent with the current labeling approved for OTC vaginal antifungal drug products under new drug applications (Ref. 1). That labeling states that the product ''cures most vaginal yeast infections.''

Accordingly, the agency is proposing to revise the indications in § 333.250(b)(1)(i) and (b)(2)(i) to add the word ''most'' after the introductory parenthetical ''Select one of the

following'' choices and to add the word ''most'' in § 333.250(b)(2)(ii) after the word ''up.'' The agency points out that this concept of ''treats most'' or ''cures most'' also needs to be used whenever a manufacturer uses the alternative labeling approaches allowed by 21 CFR 330.1(c)(2)(ii) or (c)(2)(iii) or whenever a general statement containing this information appears in the labeling of the product (e.g., on the principal display panel).

IV. Proposed Effective Date

The agency is proposing that any final rule that may issue based on this proposal become effective 12 months after its date of publication in the **Federal Register**. The agency considers this new labeling an improvement to the current labeling, but recognizes that OTC topical antifungal drug products have used the current monograph labeling for almost 6 years. Therefore, to reduce relabeling costs for manufacturers of these products, the agency will consider an 18-month effective date for any final rule that may issue based on this proposal. This longer effective date would enable manufacturers to use up existing labeling and implement the new labeling in the normal course of reordering labeling for these products. The agency invites specific comment on this extended effective date.

V. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities.

Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*) requires that agencies prepare a written statement and economic analysis before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

The agency believes that this proposed rule is consistent with the principles set out in the Executive Order and in these two statutes. The purpose of this proposed rule is to make a minor revision in the indications for OTC topical antifungal drug products. This revision should improve consumers' self use of these drug products by better informing them about what they can expect from using the products.

Manufacturers of these products will incur minor costs to relabel their products to revise the indications statement and, in some cases, other statements that appear in product labeling. The agency has been informed that relabeling costs of the type required by this proposed rule generally average about $2,000 to $3,000 per stock keeping unit (SKU) (individual products, packages, and sizes). The agency is aware of approximately 50 manufacturers that together produce about 200 SKU's of OTC topical antifungal drug products marketed under the monograph. There may be a few additional small manufacturers or products in the marketplace that are not identified in the sources FDA reviewed. Assuming that there are about 200 affected OTC SKU's in the marketplace, total one-time costs of relabeling would be $400,000 to $600,000. The agency believes the actual cost could be lower for several reasons. Most of the label changes will be made by private label manufacturers that tend to use simpler and less expensive labeling. In addition, the agency is considering and inviting public comment on an 18-month effective date for the final rule, rather than the standard 12-month effective date. This extended effective date may allow the new labeling to be implemented concurrently with the general labeling changes required by the new OTC drug labeling format (64 FR 13254, March 17, 1999). The agency believes that these actions provide substantial flexibility and reductions in cost for small entities.

The agency considered but rejected several labeling alternatives: (1) A shorter implementation period, and (2) an exemption from coverage for small entities. While the agency would like to have this new labeling in place as soon as possible, it considers a period less than 1 year difficult for manufacturers to implement and not critical in this situation. The agency does not consider an exemption for small entities appropriate because consumers who use those manufacturers' products would not have the most recent information about these products.

This analysis shows that this proposed rule is not economically significant under Executive Order 12866 and that the agency has undertaken important steps to reduce the burden to small entities. Nevertheless, some entities may incur some impacts, especially private label manufacturers that provide labeling for a number of the affected products. Thus, this economic analysis, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis, as required under the Regulatory Flexibility Act. Finally, this analysis shows that the Unfunded Mandates Reform Act does not apply to the proposed rule because it would not result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million.

VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the proposed indications statements are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VII. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that is categorically excluded from the preparation of an environmental assessment because these actions, as a class, will not result in the production or distribution of any substance and therefore will not result in the production of any substance into the environment.

VIII. Request for Comments

Interested persons may, on or before October 20, 1999, submit to the Dockets Management Branch (address above) written comments on the proposed regulation. Written comments on the agency's economic impact determination may be submitted on or before October 20, 1999. Three copies of all 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IX. Reference

The following reference has 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. Approved labeling from new drug applications for OTC vaginal antifungal drug products.

List of Subjects in 21 CFR Part 333

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 333 be amended as follows:

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

1. The authority citation for 21 CFR part 333 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 333.250 is amended by revising paragraphs (b)(1)(i), (b)(2)(i), and (b)(2)(ii) to read as follows:

§ 333.250 Labeling of antifungal drug products.

* * * * *

(b) * * *

(1) * * * (i) (Select one of the following: ''Treats,'' ''For the treatment of,'' ''For effective treatment of,'' ''Cures,'' ''For the cure of,'' ''Clears up,'' or ''Proven clinically effective in the treatment of'') ''most'' (select one condition from any one or more of the following groups of conditions:

* * * * *

(2) * * * (i) (Select one of the following: ''Clinically proven to prevent,'' ''Prevents,'' ''Proven effective in the prevention of,'' ''Helps prevent,'' ''For the prevention of,'' ''For the prophylaxis (prevention) of,'' ''Guards against,'' or ''Prevents the recurrence of'') ''most'' (select one of the following: ''Athlete's foot,'' ''athlete's foot (dermatophytosis),'' ''athlete's foot (tinea pedis),'' or ''tinea pedis (athlete's foot)'') ''with daily use.''

(ii) In addition to the information identified in paragraph (b)(2)(i) of this section, the labeling of the product may contain the following statement: ''Clears up most athlete's foot infection and with daily use helps keep it from coming back.''

* * * * *

Dated: July 14, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–18699 Filed 7–21–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01–99–060]

RIN 2115–AA97

Safety Zone: Perth Amboy Fireworks, Raritan River, NJ

AGENCY: Coast Guard, DOT.

ACTION: Withdrawal of notice of proposed rulemaking.

SUMMARY: The Coast Guard is withdrawing its notice of proposed rulemaking to establish a temporary safety zone in the Raritan River for the Perth Amboy, NJ fireworks display. The event has been cancelled by the sponsor. Therefore, the rule is no longer needed and the Coast Guard is terminating further rulemaking under docket number 99–060.

DATES: The notice of proposed rulemaking is withdrawn effective July 22, 1999.

FOR FURTHER INFORMATION CONTACT: Lieutenant J. Lopez, Waterways Oversight Branch, Coast Guard Activities New York (718) 354–4193.

SUPPLEMENTARY INFORMATION: On June 7, 1999, the Coast Guard published a notice of proposed rulemaking entitled ''Safety Zone: Perth Amboy Fireworks, Raritan River, NJ'' in the **Federal Register** (64 FR 30274). The Perth Amboy Chamber of Commerce has cancelled the event, therefore the rulemaking for this event is no longer necessary. The Coast Guard is withdrawing the NPRM and terminating further rulemaking under docket number 99–060.

Dated: July 14, 1999.

R.E. Bennis,

Captain, U.S. Coast Guard, Captain of the Port, New York.

[FR Doc. 99–18703 Filed 7–21–99; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD08–99–031]

RIN 2115–AE47

Drawbridge Operating Regulations; Mississippi River, Iowa and Illinois

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes a temporary change to the regulation governing the Rock Island Railroad and Highway Drawbridge, Mile 482.9, Upper Mississippi River. Under the proposed rule the drawbridge need not open for vessel traffic and may remain in the closed-to-navigation position from 7:30 a.m. to 11:30 a.m. on September 26, 1999. This temporary rule would allow the scheduled running of the Quad City Marathon as part of a local community event.

DATES: Comments must be received on or before August 23, 1999.

ADDRESSES: Comments can be mailed to Commander, Eighth Coast Guard District (obr), 1222 Spruce Street, St. Louis, Missouri 63103–2832, between 7 a.m. and 4 p.m., Monday through Friday except Federal holidays. Comments will become part of the public docket and will be available for copying and inspection in room 2.107f at the same address.

FOR FURTHER INFORMATION CONTACT: Roger K. Wiebusch, Bridge Administrator; Eighth Coast Guard District, Bridge Branch, 1222 Spruce Street, St. Louis, Missouri 63103–2832, telephone 314–539–3900 extension 378.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested parties to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD 08–99–031) and the specific section of this document to which each comment applies, and give the reason for each comment. Please submit two copies of all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgement of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments. The Coast Guard plans no public hearing. Persons may request a public hearing in writing to the address under **ADDRESSES**. The request should include the reasons why a hearing would be beneficial. If the Coast Guard determines that the opportunity for oral presentations will aid this rulemaking, it will hold a public hearing at a time and place announced by a notice in the **Federal Register**.