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 gauge, in accordance with a method approved by the Manager, International Branch, ANM–116. Operators shall submit their requests through an 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 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.


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
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:
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
Cost Guard
33 CFR Part 165
[CGD01–99–060]
RIN 2115–AA97
Safety Zone: Perth Amboy Fireworks, Raritan River, NJ
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.