the General Counsel, the General Counsel will promptly notify the affected member or employee in writing of his or her intent to forward the matter to the Commission. Any member or employee so affected will be afforded an opportunity to be heard by the Commission through written submission.

* * * * *

By the Commission on February 1, 2002.

Jean A. Webb,

Secretary.

[FR Doc. 02–2935 Filed 2–7–02; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

[Docket No. 99N–4063]

RIN 0910–AA01

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the final monograph for over-the-counter (OTC) topical antifungal drug products to add the ingredient clotrimazole as generally recognized as safe and effective for the treatment of athlete's foot, jock itch, and ringworm. This final rule is part of FDA's ongoing review of OTC drug products.

DATES: This rule is effective March 11, 2002.

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 six antifungal active ingredients used for the treatment of athlete's foot, jock itch, and ringworm and one ingredient used for the prevention of athlete's foot. The monograph provides that two ingredients may contain professional labeling (may be provided to health professionals but not to the general public) for the treatment of superficial infections caused by yeast (*Candida albicans*).

In the **Federal Register** of May 29, 2001 (66 FR 29059), FDA proposed to amend the final monograph to add the antifungal ingredient clotrimazole at a 1-percent concentration as generally recognized as safe and effective for the treatment of athlete's foot, jock itch, and ringworm. The agency discussed safety and effectiveness data for clotrimazole for these uses and noted it has been marketed OTC in the United States since 1989 under new drug applications (NDAs) in cream, lotion, and solution dosage forms, with a significant amount marketed in the United States and other countries since 1990.

In response to the proposal, the agency received one comment, which is on public display in the Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The comment supported the agency's determination that clotrimazole has been marketed to a material extent and for a material time as a topical antifungal drug and that, based on the available data, it can be generally recognized as safe and effective for the treatment of athlete's foot, jock itch, and ringworm and included in the OTC drug monograph for this class of products.

II. The Agency's Final Conclusions

The agency has determined that clotrimazole in a 1-percent concentration has been marketed to a material extent and for a material time as a topical antifungal drug. Based on the available data, it can be generally recognized as safe and effective for the treatment of athlete's foot (tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis) and included in the OTC drug monograph for this class of products. Therefore, the agency is adding clotrimazole 1-percent as new paragraph (g) in § 333.210. Any product containing clotrimazole that is marketed under the monograph must use all of the labeling that is required by the final monograph (part 333, subpart C) and must follow the content and format requirements in 21 CFR 201.66.

This final rule does not apply to clotrimazole marketed OTC as an antifungal agent in intravaginal drug products labeled for the treatment of vaginal yeast infections. The existing monograph for topical antifungal drug products does not contain any claims for intravaginal use.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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.

Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits 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 concludes that this final rule is consistent with the principles set out in the Executive order and in these two statutes. The final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. Further, since this final rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation, FDA need not prepare additional analyses under the Unfunded Mandates Reform Act.

The purpose of this final rule is to include clotrimazole 1-percent in the monograph for OTC topical antifungal drug products. This rule allows current manufacturers of these products to market their products under the OTC drug monograph instead of an NDA and enables other manufacturers who wish to market clotrimazole products OTC to enter the marketplace without having to obtain an NDA. In both cases, there will be cost savings from marketing without an NDA.

When current manufacturers market these products under the OTC drug monograph, they should incur only minor costs to relabel their products to meet the monograph. Some manufacturers may have to add a warning that was included in the final monograph, but not required when

some products containing clotrimazole were approved for OTC marketing under an NDA. These manufacturers can make this change whenever they are ready to order new product labeling. Manufacturers have informed the agency that this type of relabeling cost generally averages about $2,000 to $3,000 per stock keeping unit (SKU) (individual products, packages, and sizes). Based on information in the agency's Drug Listing System, there are less than 10 manufacturers and distributors that together produce about 25 SKUs of OTC topical antifungal drug products that contain clotrimazole. Assuming that there are about 25 affected OTC SKUs in the marketplace, total one-time costs of relabeling would be $50,000 to $75,000. Because the manufacturers can make the changes when they are ready to reorder product labeling stock, the incremental costs of the added warning will, for the most part, be mitigated. In making this change, these manufacturers would save money by eliminating all costs associated with maintaining an NDA. Likewise, other manufacturers who now wish to market topical clotrimazole drug products will be able to enter the marketplace without the costs associated with an NDA. Their costs would involve the standard startup costs of any OTC drug marketed under the monograph.

Because no small firms will be adversely affected, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

IV. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements for clotrimazole 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 existing monograph labeling is 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)).

V. Environmental Impact

The agency has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

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, 21 CFR part 333 is 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 333.210 is amended by adding paragraph (g) to read as follows:

§ 333.210 Antifungal active ingredients.

* * * * *

(g) Clotrimazole 1 percent.

Dated: January 30, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–3079 Filed 2–7–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 821

[Docket No. 00N–1034]

Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the medical device tracking regulation. FDA is making substantive changes to revise the scope of the regulation and add certain patient confidentiality requirements, and nonsubstantive changes to remove outdated references and simplify terminology. These revisions are made to conform the regulation to changes made in section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act) by the FDA Modernization Act of 1997 (FDAMA), and to simplify certain requirements.

DATES: This rule is effective May 9, 2002. The information collection provisions of this final rule have been submitted to the Office of Management and Budget (OMB) for review. Prior to the effective date of this final rule, FDA will publish in the **Federal Register** a notice announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule.

FOR FURTHER INFORMATION CONTACT: Chester T. Reynolds, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4618.

SUPPLEMENTARY INFORMATION:

I. Current Statutory Tracking Provisions (As Amended by FDAMA)

Section 211 of FDAMA (Public Law 105–115) became effective on February 19, 1998. It amended the previous tracking provisions in section 519(e)(1) and (e)(2) of the act (21 U.S.C. 360i(e)(1) and (e)(2)) that were added by the Safe Medical Devices Act (SMDA). Unlike the tracking provisions under SMDA, which required tracking for any device meeting certain criteria, FDAMA allows FDA discretion in applying tracking requirements to devices that meet certain criteria and provides that tracking requirements can be imposed only after FDA issues an order.

Current section 519(e)(1) of the act, as amended by FDAMA, provides that FDA may by order require a manufacturer to adopt a method of tracking a class II or class III device if: (1) Its failure would be reasonably likely to have serious adverse health consequences, or (2) it is intended to be implanted in the human body for more than 1 year, or (3) it is a life-sustaining or life-supporting device used outside a device user facility. FDA interprets the discretion inherent in the language ''may by order require'' tracking to allow the agency to consider additional relevant factors in determining whether to issue a tracking order for a device that meets the statutory threshold tracking criteria set out in current section 519(e)(1) of the act.

As amended by FDAMA, current section 519(e)(2) of the act provides that patients receiving a device subject to