

antifungal drug products. The agency rejected an exemption for small entities because the new labeling information is also needed by consumers who purchase products marketed by those entities.

Under the Unfunded Mandates Reform Act, FDA is not required to prepare a statement of costs and benefits for this final rule because this final rule is not expected to result in any one-year expenditure that would exceed \$100 million adjusted for inflation.

This analysis shows that the agency has considered the burden to small entities. Thus, this economic analysis, together with other relevant sections of this document, serves as the agency's final regulatory flexibility analysis, as required under the Regulatory Flexibility Act.

V. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this final rule 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 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)).

VI. 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.

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 333.250 is amended by revising paragraphs (b)(1)(i) introductory text, (b)(2)(i) introductory text, 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."

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Dated: August 15, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 3399]

Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended—Addition of Department of Labor for Approval of Certain Nonimmigrant Petitions

AGENCY: Department of State.

ACTION: Interim rule.

SUMMARY: This rule adds the Department of Labor as the source of approved petitions to accord the status of temporary agricultural workers, H-2A, in lieu of the Immigration and Naturalization Service (INS).

DATES: This interim rule is effective November 13, 2000. Written comments are invited and must be received on or before October 30, 2000.

ADDRESSES: Written comments may be submitted, in duplicate, to the Chief, Legislation and Regulations Division,

Visa Services, Department of State, Washington, DC 20520-0106.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520-0106, (202) 663-1204, e-mail odomhe@state.gov, or fax at (202) 663-3898.

SUPPLEMENTARY INFORMATION: The current regulation relating to temporary workers, at 22 CFR 41.53(a)(2), requires receipt by a consular officer of a petition approved by the INS (or notification of an INS-approved extension of stay in H status) as a basis for the issuance of a temporary worker visa to an otherwise eligible alien. This interim rule amends that regulation to accord with new INS and Department of Labor (DOL) regulations. They reflect a recent INS delegation to the Department of Labor of the sole authority to approve (or disapprove) petitions filed to accord the status of temporary agricultural worker on certain aliens. This interim rule will permit consular officers to accept petitions in this category approved by the Department of Labor. The amendments in this rule consist of an insert relating to the DOL approval of such petitions in both 22 CFR 41.53(a)(2) and 41.53(b).

Regulatory Analysis and Notices

Administrative Procedure Act

The Department is publishing this rule as an interim rule, with a 60-day provision for public comments, based on the "good cause" exceptions set forth at 5 U.S.C. 553(b)(3)(B) and 553(d)(3). The change in INS and DOL regulations will become effective on November 13, 2000, as will this rule. That change simplifies and expedites procedures which benefit all employers of temporary agricultural workers, and therefore is in the interest of the United States. This rule gives consular effect to that change. The substance of this rule results solely from actions taken by the INS and DOL, over which the Department has no control.

Regulatory Flexibility Act

Pursuant to section 605 of the Regulatory Flexibility Act, the Department has assessed the potential impact of this rule, and the Assistant Secretary for Consular Affairs hereby certifies that it is not expected to have a significant economic impact on a substantial number of small entities and will benefit those that engage temporary agricultural workers.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100 million in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

The Department of State does not consider this rule to be a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review, and the Office of Management and Budget has waived its review process under section 6(a)(3)(A).

Executive Order 13132

This regulation will not 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. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement.

Paperwork Reduction Act

This rule does not impose any new reporting or record-keeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 41

Aliens, Passports and visas.

Accordingly, the Department of State amends 22 CFR Chapter I as set forth below.

PART 41—[AMENDED]

1. The authority citation for part 41 continues to read as follows:

Authority: 8 U.S.C. 1104

§ 41.53 [AMENDED]

2. Amend Section 41.53 as follows:
 a. In paragraph (a)(2), insert ", or by the Department of Labor in the case of temporary agricultural workers" following the phrase "approval by INS."
 b. In paragraph (b), insert "or by the Department of Labor" following "Immigration and Naturalization Service."

Dated: July 27, 2000.

Maura Harty,

Acting Assistant Secretary for Consular Affairs, Department of State.

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DEPARTMENT OF STATE**22 CFR Part 41**

[Public Notice 3400]

Documentation of Nonimmigrants Under the Immigration and Nationality Act, As Amended—Waiver of Nonimmigrant Visa Fees for Members of Observer Missions to the United Nations

AGENCY: Department of State.

ACTION: Interim rule.

SUMMARY: Current regulations contain a waiver of visa application and issuance fees for aliens coming to the United States in various diplomatic classifications, including those related to international organizations. This rule extends that provision to include persons who are members of observer missions to the United Nations who apply for B-1 visas to enter as participants in their U.N. observer missions.

DATES: This rule is effective August 29, 2000.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, D.C. 20520-0106, (202) 663-1204.

SUPPLEMENTARY INFORMATION: The current regulation governing the waiver of visa fees for diplomats, on a reciprocal basis or as provided in the Headquarters Agreement with the United Nations, identifies the beneficiaries of the waiver by the classification of the visas they seek. In some instances, members of missions invited by the United Nations in observer status do not qualify for any of the applicable classifications and, instead, obtain B-1 visas for the purpose of attendance at the United Nations in

observer capacity. This amendment will bring such individuals under the same umbrella with regard to visa fees as others at the United Nations.

Is This Within the Agreement With the United Nations?

Yes. Article 11 of the Headquarters Agreement identifies the persons who are to be granted certain privileges. The fifth category, although not using the term "observer mission", clearly encompasses members of such units. Article 13 requires, among other things, that visas for persons covered by Article 11 be issued gratis.

Why Now, and Not Earlier?

In the past, most persons entering for the purpose of attendance at the United Nations obtained visas in one of the identified classifications. The few who didn't faced fees of negligible amounts and did not object to them. Over time, however, some reciprocal visa issuance fees, in particular, have become substantial, and the unintended but obvious inequity became a problem. This change in the regulation rectifies that problem.

Regulatory Analysis and Notices

Interim Rule

The implementation of this rule as an interim rule, with a 60-day provision for post-promulgation public comments, is based on the "good cause" exceptions set forth at 5 U.S.C. 553(b)(3)(B) and 553(d)(3). The benefit conferred fulfills the international responsibility of the United States as host country. Delay of the benefit for public notice and comment is unnecessary.

The Regulatory Flexibility Act

Pursuant to Section 605 of the Regulatory Flexibility Act, the Department has assessed the potential impact of this rule, and the Assistant Secretary for Consular Affairs hereby certifies that it is not expected to have a significant economic impact on a substantial number of small entities.

Executive Order 12372 and Executive Order 13132

The rule does not directly affect states or local governments or Federal relationships, does not create unfunded mandates, and does not have sufficient federalism implications to warrant preparation of a federalism assessment.

5 U.S.C. Chapter 8

As required by 5 U.S.C., chapter 8, the Department has screened this rule and determined that it is not a major rule, as defined in 5 U.S.C. 80412.