

Dated: October 20, 1999.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99-27879 Filed 10-27-99; 8:45 am]

BILLING CODE 8010-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801, 878, and 880

[Docket No. 98N-0313]

Surgeon's and Patient Examination Gloves; Reclassification; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to January 27, 2000, the comment period for the proposed rule that appeared in the **Federal Register** of July 30, 1999 (64 FR 41710). The proposed rule would reclassify all surgeon's and patient examination gloves as class II medical devices. The agency is taking this action in response to two requests for extension of the comment period. This extension of the comment period is intended to allow interested persons additional time to submit comments on the proposed rule.

DATES: Written comments by January 27, 2000.

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

FOR FURTHER INFORMATION CONTACT: Donald E. Marlowe, Center for Devices and Radiological Health (HFZ-100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4777.

SUPPLEMENTARY INFORMATION:

I. Extension of Comment Period

In the **Federal Register** of July 30, 1999, FDA published a proposed rule to reclassify all surgeon's and patient examination gloves as class II medical devices. FDA is soliciting comments and information from interested persons concerning the reclassification of these devices into four categories (powdered surgeon's gloves, powder-free surgeon's gloves, powdered patient examination gloves, and powder-free patient examination gloves), and it proposed special controls consisting of a "Medical

Glove Guidance Manual" and labeling requirements that address protein and powder content.

FDA received one request from a manufacturer of medical gloves and another request from a voluntary standard setting organization to extend the comment period an additional 90 days. The manufacturer and the voluntary standard setting organization requested additional time to allow the American Society for Testing and Materials (ASTM), a voluntary standard setting organization, to complete its balloting for revisions of its standards to include a recommended maximum powder limit in its standards for latex surgeon's gloves, latex patient examination gloves, polyvinyl medical gloves, and nitrile patient examination gloves. The manufacturer and the voluntary standard setting organization wanted the additional time to allow FDA and others to consider ASTM's recommendations along with FDA's proposal. In response to the letters, FDA is extending the comment period for 90 additional days. Elsewhere in this issue of the **Federal Register**, FDA is announcing an extension of the comment period for the draft guidance entitled "Medical Glove Guidance Manual."

II. Comments

Interested persons may, on or before January 27, 2000, submit to the Dockets Management Branch (address above) written comments regarding the proposed rule. Two copies of any 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 21, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99-28109 Filed 10-27-99; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Parts 40 and 42

[Public Notice 3122]

Documentation of Immigrants and Nonimmigrants Under the Immigration and Nationality Act, as Amended—Change in Procedures for Payment of Immigrant Visa Fees

AGENCY: Department of State.

ACTION: Proposed rule, with request for comments.

SUMMARY: This rule changes the regulation relating to immigrant visa fees to require the applicant to pay the application processing fee prior to the time of application. Related changes are made to ensure that this fee change is not misunderstood as changing the long-held Department of State principle that an alien has "applied for a visa" only when, in the case of nonimmigrants, the application (with processing fee or evidence of the prior payment of the processing fee) has been accepted for adjudication or, in the case of immigrants, the applicant has presented all of the required forms and the processing fee (or evidence of the prior payment of the processing fee) and has attested to the application under oath or affirmation before the consular officer.

DATES: Comments must be received on or before December 27, 1999.

ADDRESSES: For written comments, please contact H. Edward Odom, 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.

SUPPLEMENTARY INFORMATION: The basic purpose of this regulation is to modify the point in time at which an immigrant visa applicant must pay the application processing fee. The regulation defining the time at which applications have been "made" is being added to prevent any confusion from arising as a result of the revised terminology in the fee regulation.

Why is it necessary to alter the time when the applicant must pay the immigrant visa processing fee? An application fee is not a penalty for applying for a visa; it is intended to cover the costs of the processing required in connection with such an application. The current regulation calls for payment of the application fee prior to the formal application interview, normally when the applicant is at the embassy or consulate on the day of the visa interview. However, services to the applicant, and costs incurred by the government, begin long before that time. Records must be established by the Department of State as soon as an approved petition is received from the Immigration and Naturalization Service and a number of processing steps then ensue. As the purpose of a processing fee is to cover these costs, it is appropriate that the fee be collected at

an earlier point in the procedures. However, due to heavy immigrant visa demand, many immigrant visa registrants may wait years after registration before reaching the point of receiving a request from the Department to obtain the documents needed to support their visa application. In recognition of this, the Department believes it would be unfair to collect the processing fee at the time of registration. On the other hand, once an applicant has been informed that a visa number is expected to become available and instructed to obtain such supporting documents, it is quite reasonable to collect the processing fee at that point. Doing so may also permit the Department to develop more efficient fee collection procedures. Provision is made for refund of the fee if, for reasons attributable only to the U.S. Government, the applicant is precluded from proceeding to the remaining steps in making the application after payment of the fee.

"Making" an application. The point at which the application is made is here made explicit in the regulation.

Why is it necessary to clarify the definition of "making an application" in immigrant visa cases? Because immigrant visa cases are quite complex and involve many steps along the way, some people speak of "having applied for a visa" when the only thing that has happened to that point is that a relative or prospective employer has filed a petition to accord the alien a particular status under the immigration laws. Sometimes such persons believe that when they have been told to obtain supporting documents, or to complete a biographic form, they have now "applied." This regulation makes it clear that a person has "applied" for an immigrant visa when he or she has presented all required forms, documents and processing fees (or evidence of the prior payment of the processing fees) and has been interviewed by a consular officer and has attested to the veracity and validity of the documents submitted. Except as otherwise provided by regulation (§§ 42.62(a) and 42.63(a)(2)), the law (8 U.S.C. 1202(e)) requires the appearance and the taking of an oath before a consular officer. Therefore, it has always been the expressed view of the Department, implicit throughout its regulations, that an alien cannot be considered to have "applied" for an immigrant visa until this requirement is fulfilled. This distinction may become important in instances in which aliens must apply for a visa by a particular date. To the extent that some people might mistake payment of the application processing

fee for the making of an application, it is useful to reiterate this point at this time.

Why should the definition of "making an application for a visa" be clarified in the case of nonimmigrant visas?

Normally, a consular officer takes action on a nonimmigrant visa application when the officer receives required forms, documents and fees or evidence of the prior payment of the fees. Thus, the nonimmigrant visa application is not as susceptible to be subject to misunderstanding as in the case of immigrant visas. This rule does, however, clarify the fact that signing the form and giving it to a travel agent for presentation, or mailing it to a consulate, or leaving it in the consular mailbox, is not, in itself, sufficient. It must also be received by a consular officer and be accepted for adjudication.

Regulatory Analysis and Notices

Proposed Rule

This is a proposed rule, with a 60-day provision for public comments.

The Regulatory Flexibility Act

Pursuant to § 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.

E.O. 12988 and E.O. 12866

This rule has been reviewed as required under E.O. 12998 and determined to be in compliance therewith. This rule is exempt from review under E.O. 12866, but has been reviewed internally by the Department to ensure consistency therewith. The rule does not directly affect states or local governments or Federal relationships and does not create unfunded mandates.

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.

Paperwork Reduction Act

This rule does not create any new paperwork requirements.

List of Subjects in 22 CFR Parts 40 and 42

Aliens, Immigrants, Passports and visas.

In view of the foregoing, 22 CFR part 40 and 22 CFR part 42 are amended as follows:

PART 40—[AMENDED]

1. The authority citation for part 40 is revised to read as follows:

Authority: 8 U.S.C. 1104.

2. Section 40.1 is amended by redesignating paragraphs (l), (m), (n), (o), (p), (q), (r), and (s) as paragraphs (m), (n), (o), (p), (q), (r), (s), and (t), respectively, and adding a new paragraph (l) to read as follows:

§ 40.1 Definitions

* * * * *

(l) *Make or file an application for a visa* means: (1) For a nonimmigrant visa applicant, submitting for formal adjudication by a consular officer of a completed Form OF-156, with any required supporting documents and the requisite processing fee or evidence of the prior payment of the processing fee when such documents are received and accepted for adjudication by the consular officer;

(2) for an immigrant visa applicant, personally appearing before a consular officer and verifying by oath or affirmation the statements contained on the Form OF-230 and in all supporting documents, having previously submitted all forms and documents required in advance of the appearance and paid the visa application processing fee.

* * * * *

PART 42—[AMENDED]

3. The authority citation for part 42 continues to read:

Authority: 8 U.S.C. 1104.

4. Section 42.71 is amended by revising paragraph (b) to read as follows:

§ 42.71 Authority to issue visas; visa fees.

* * * * *

(b) *Immigrant visa fees.* The Secretary of State prescribes separate fees for the processing of immigrant visa applications and for the issuance of immigrant visas thereafter to persons whose applications are approved. An individual registered for immigrant visa processing must pay the processing fee upon being notified that a visa is expected to become available in the near future and being requested to obtain the supporting documentation needed to apply formally for a visa, in accordance with instructions received with such notification. The fee must be made before the applicant will receive an appointment to appear and make application before a consular officer. The applicant must pay the issuance fee after the consular officer has completed the visa interview and approved

issuance of the visa, but prior to its issuance. A fee collected for the processing of an immigrant visa application is refundable only if the principal officer of a post or the officer in charge of a consular section determines that the notification of prospective visa availability was sufficiently erroneous to preclude the applicant from benefiting from the processing. A fee collected for the issuance of an immigrant visa is refundable only if either of such officers determines that the visa was issued in error or could not be used as a result of U.S. Government actions over which the alien had no control and for which the alien was not responsible in whole or in part.

Dated: September 10, 1999.

Maura A. Harty,

Acting Assistant Secretary of State for Consular Affairs.

[FR Doc. 99-24439 Filed 10-27-99; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-252487-96]

RIN 1545-AX25

Inbound Grantor Trusts With Foreign Grantors; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document provides notice of cancellation of a public hearing on proposed regulations relating to inbound grantor trusts with foreign grantors.

DATES: The public hearing originally scheduled for Tuesday, November 2, 1999, at 10 a.m., is canceled.

FOR FURTHER INFORMATION CONTACT: Guy Traynor of the Regulations Unit, Assistant Chief Counsel (Corporate), (202) 622-7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and notice of public hearing that appeared in the **Federal Register** on August 10, 1999, (64 FR 43323), announced that a public hearing was scheduled for November 2, 1999, at 10 a.m., room 2615, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC 20224. The subject of the public hearing is proposed regulations under section 671 of the Internal Revenue Code. The

public comment period for these proposed regulations expired on October 12, 1999.

The notice of proposed rulemaking and notice of public hearing, instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be addressed. As of October 18, 1999, no one has requested to speak. Therefore, the public hearing scheduled for November 2, 1999, is canceled.

Cynthia E. Grigsby,

Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 99-28038 Filed 10-27-99; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG-101519-97]

RIN 1545-AV00

Withdrawal of Notice of Federal Tax Lien in Certain Circumstances; Hearing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of public hearing on proposed rulemaking.

SUMMARY: This document contains a notice of public hearing on proposed regulations relating to the withdrawal of notice of federal tax liens in certain circumstances.

DATES: The public hearing is being held on November 30, 1999, at 10 a.m. The IRS must receive outlines of the topics to be discussed at the hearing by November 16, 1999.

ADDRESSES: The public hearing is being held in Room 2615, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the 10th Street entrance, located between Constitution and Pennsylvania Avenues, NW. In addition, all visitors must present photo identification to enter the building.

Mail outlines to: CC:DOM:CORP:R (REG-101519-97), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Hand deliver outlines Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG-101519-97), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Submit outlines electronically via the Internet by selecting the "Tax Regs"

option on the IRS Home Page, or by submitting them directly to the IRS Internet site at http://www.irs.gov/tax_regs/reglist.html.

FOR FURTHER INFORMATION CONTACT: Concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing LaNita Van Dyke, (202) 622-7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is the notice of proposed regulations (REG-101519-97) that was published in the **Federal Register** on Wednesday, June 30, 1999 (64 FR 35102).

The rules of 26 CFR 601.601(a)(3) apply to the hearing.

Persons who have submitted written comments and wish to present oral comments at the hearing, must submit an outline of the topics to be discussed and the amount of time to be devoted to each topic (signed original and eight (8) copies) by Tuesday, November 16, 1999.

A period of 10 minutes is allotted to each person for presenting oral comments.

After the deadline for receiving outlines has passed, the IRS will prepare an agenda containing the schedule of speakers. Copies of the agenda will be made available, free of charge, at the hearing.

Because of access restrictions, the IRS will not admit visitors beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this document.

Cynthia E. Grigsby,

Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 99-28130 Filed 10-27-99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TX-79-1-7328b, FRL-6459-7]

Approval and Promulgation of Implementation Plans; Texas; Repeal of Board Seal Rule and Revisions to Particulate Matter Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to take direct final action approving revisions