

Dated: October 20, 1999.

Margaret H. McFarland,

Deputy Secretary.

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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