

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0030]

Draft Guidance for Industry and Food and Drug Administration Staff; Recommended Warning for Surgeon's Gloves and Patient Examination Gloves That Use Powder; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Recommended Warning for Surgeon's Gloves and Patient Examination Gloves that Use Powder." This draft guidance document provides a recommended warning statement related to medical gloves that contain powder or use donning or dusting powder, specifically surgeon's gloves and patient examination gloves (medical gloves that use powder). FDA is concerned about the potential adverse health effects from the use of powder on medical gloves and is recommending that the labeling for powdered medical gloves provide a warning related to the potential health effects. This draft guidance is not final nor is it in effect at this time. Elsewhere in this issue of the **Federal Register**, FDA is announcing the establishment of a public docket to receive comments related to surgeon's gloves and patient examination gloves that contain or use donning or dusting powder.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 9, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Recommended Warning for Surgeon's Gloves and Patient Examination Gloves That Use Powder" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. *See* the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Subhas Malghan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, rm. 3204, Silver Spring, MD 20993-0002, 301-796-2548, Subhas.malghan@fda.hhs.gov; or Sheila Murphey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2510, Silver Spring, MD 20993-0002, 301-796-6302, Sheila.murphey@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Medical gloves are a significant factor in the protection of both patients and health care personnel in the United States. Health care personnel rely on medical gloves as a barrier against transmission of infectious diseases and contaminants when conducting surgery as well as in more limited interactions with patients.

Following the recognition of acquired immunodeficiency syndrome (AIDS) as a major public health concern and recommendations from the Centers for Disease Control and Prevention that health care workers use appropriate barrier precautions to prevent exposure to the human immunodeficiency virus (HIV), FDA recognized the need for greater assurance that cross-contamination between patients and health care workers be prevented. In the **Federal Register** of January 13, 1989 (54 FR 1602), FDA revoked the exemption for patient examination gloves from certain current good manufacturing practice requirements in order to assure that manufacturers provide an acceptable manufacturing quality level. FDA similarly revoked the exemption from premarket notification requirements for patient examination gloves.

On December 12, 1990 (55 FR 51254), FDA published regulations describing certain circumstances under which surgeon's and patient examination gloves would be considered adulterated. The regulations established the sampling plans and test methods for glove leakage defects that the Agency would use to determine whether gloves were adulterated. (*See* 21 CFR 800.20).

Subsequently, FDA initiated inspections of glove manufacturers to assure conformance with the acceptable quality levels identified in the regulation.

In 1997, FDA issued the "Medical Glove Powder Report" discussing the potential adverse health effects of medical glove powder, along with alternatives and current market information available at that time. Adverse health events reviewed by the Medical Glove Powder Report included: (1) Aerosolized powder on natural rubber latex (NRL) gloves carrying allergenic proteins as a cause of respiratory allergic reactions; (2) rhinitis, conjunctivitis, and dyspnea; (3) respiratory problems; (4) granuloma formation; and (5) peritoneal adhesions.

FDA is issuing this draft guidance with a recommended warning statement for powdered medical gloves. The statement should inform users of the potential adverse health effects from these devices, including foreign body reaction, formation of granulomas, and peritoneal adhesion especially with multiple surgeries. The warning should also include information on increases in respiratory ailments, and development of irritant dermatitis or Type IV allergy when glove powder is used on NRL gloves. In addition, the warning should state that powder used on NRL medical gloves can serve as a carrier for airborne allergenic natural rubber latex proteins.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the Agency's current thinking on "Recommended Warning for Surgeon's Gloves and Patient Examination Gloves that Use Powder." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used, but should address the identified risks inherent to powdered gloves.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Recommended Warning for Surgeon's Gloves and Patient Examination Gloves that Use Powder," you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send

a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1704 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 801 have been approved under

OMB control number 0910-0485. In addition, FDA concludes that the labeling statement in section 4 of the guidance does not constitute a "collection of information" under the PRA. Rather, this labeling statement is "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. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*), either electronic or written

comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 1, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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