DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-2261]

Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings." FDA is issuing this draft guidance to describe the Agency's premarket regulatory requirements and the performance testing needed to support liquid barrier claims for gowns intended for use in health care settings. This draft guidance is being issued in light of the public health importance of personal protective equipment in health care settings and the recognition that terminology used to describe gowns has evolved, including by industry, the standards community, and health care professionals. This draft guidance is not final nor is it in effect at this time.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Elizabeth Claverie, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2508, Silver Spring, MD 20993-0002, 301-796-6298.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued a final rule on June 24, 1988 (53 FR 23874), defining "surgical apparel" under 21 CFR 878.4040. Under this 1988 final rule, surgical gowns and surgical masks were classified as Class II subject to premarket review under section 510(k) (21 U.S.C. 351) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), and surgical apparel other than surgical gowns and surgical masks were classified as Class I also subject to 510(k) premarket review requirements. On January 14, 2000, FDA issued a final rule (65 FR 2318) to designate as

exempt from premarket notification requirements surgical apparel other than surgical gowns and surgical masks, subject to the limitations of exemptions under 21 CFR 878.9, which includes requiring a premarket notification for devices intended for a use different from the intended use of a legally marketed device in that generic type of device.

Since the original 1988 final rule, a number of terms have been used to refer to gowns intended for use in health care settings including, but not limited to, surgical gowns, isolation gowns, surgical isolation gowns, nonsurgical gowns, procedural gowns, and operating room gowns. In 2004, FDA recognized the consensus standard American National Standards Institute/Association of the Advancement of Medical Instrumentation (ANSI/AAMI) PB70:2003, "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities." ANSI/AAMI PB 70 utilized new terminology for barrier performance of gowns. This terminology described and assessed the barrier protection levels of gowns and other protective apparel intended for use in health care facilities, by specifying test methods and performance results necessary to verify and validate the newly defined levels of barrier protection. The definitions and terminology used in this standard are inconsistent with FDA's historical definitions of these terms and thus have added confusion in the marketplace. The purpose of this draft guidance is to clarify and describe the premarket regulatory requirements pertaining to gowns regulated under § 878.4040 and the performance testing needed to support liquid barrier claims for gowns intended for use in health care settings.

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 represents the Agency's current thinking on performance testing to support liquid barrier claims for gowns intended for use in health care

settings. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of "Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500025 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This 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 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subparts A through D have been approved under OMB control number 0910-0625; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910-0437; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; and

the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. It is only necessary to send one set of 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, and will be posted to the docket at http://www.regulations.gov.

Dated: June 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

4164-01-P

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