redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Zivana Tezak, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 4544, Silver Spring, MD 20993, 301–796–6206, *zivana.tezak@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 9, 2015 (80 FR 54292), FDA published a notice of a public workshop with a deadline of November 25, 2015, to request comments on the workshop topics about the proposed standards-based regulatory strategy for NGS tests that produce results on variation in the human genome. Comments on the public meeting topics will inform FDA's development of such strategies.

FDA is reopening the comment period for the notice of the public workshop until December 24, 2015. The Agency believes that the extension allows adequate time for interested persons to submit comments without significantly delaying decisionmaking on these important issues.

Dated: December 3, 2015.

**Peter Lurie,**

*Associate Commissioner for Public Health Strategy and Analysis.*

[FR Doc. 2015–30937 Filed 12–8–15; 8:45 am]

**BILLING CODE 4164–01–P**

## 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; Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings.'' FDA is issuing this 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 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 FDA, industry, the standards community, and health care professionals.

**DATES:** Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2015–D–2261 for ''Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more

information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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.

**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 23856 at 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) 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 2296 at 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, cover gowns, comfort gowns, procedural gowns, and operating room gowns. The Agency has defined the term ''surgical gowns'' through existing guidance and substantial equivalence decisions to mean ''surgical apparel worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.'' 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 market place. The purpose of this 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.

In the **Federal Register** of June 30, 2015 (80 FR 37275), FDA announced the availability of the draft of this guidance. Interested persons were invited to comment by August 31, 2015. FDA considered the public comments received and revised the guidance, where applicable. Multiple comments requested revisions to the terminology used in the guidance; however, the intent of the guidance was not to change existing terminology as used by the Agency, but rather to clarify and describe the premarket regulatory requirements concerning gowns intended for use in health care settings. While the focus of any future actions on this topic may include discussion on changing terminology, such changes would require additional regulatory action and are outside the scope of this guidance. Additionally, several comments were received regarding the Agency's expectation that submitters submit a 510(k) within 60 days if they are not currently in compliance with the expectations outlined in the guidance. We continue to believe this timeframe for submission is appropriate since submitters should already have conducted the testing to support their particular liquid barrier claims. For the comments received related to specific products, FDA is encouraging submitters to contact the review Division directly or submit a pre-submission to address these concerns as it is not appropriate to address such product-specific concerns in the guidance.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Premarket Notification Requirements Concerning 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.

Dated: December 3, 2015.

**Peter Lurie,**

*Associate Commissioner for Public Health Strategy and Analysis.*

[FR Doc. 2015–30972 Filed 12–8–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–N–3015]**

### Use of Databases for Establishing the Clinical Relevance of Human Genetic Variants; Public Workshop; Reopening of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening the comment period for the notice of a public workshop that appeared in the **Federal Register** of September 9, 2015. In the notice of the public workshop, FDA requested comments on the workshop topics about the use of databases that contain information linking human genetic variations to disease, where such information has been curated by qualified professionals, to inform regulatory oversight of the clinical performance of genetic tests. The Agency is taking this action in response to requests to allow interested persons additional time to submit comments.

**DATES:** FDA is reopening the comment period for the notice of public workshop published September 9, 2015. Submit either electronic or written comments by December 24, 2015.

**ADDRESSES:** You may submit comments as follows:

**Electronic Submissions**

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

**Written/Paper Submissions**

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2015–N–3015 for ''Use of Databases for Establishing the Clinical Relevance of Human Genetic Variants.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** David Litwack, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 4548, Silver Spring, MD 20993, 301–796–6697, *ernest.litwack@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 9, 2015 (80 FR 54290), FDA published a notice of a public workshop with a deadline of November 25, 2015, to request comments on the workshop topics about the use of databases that contain information linking human genetic variations to disease, where such information has been curated by qualified professionals, to inform regulatory oversight of the clinical performance of genetic tests. Comments on the public workshop topics will inform FDA's optimization of regulatory approaches for next-generation-based in vitro diagnostics.

FDA is reopening the comment period for the notice of the public workshop until December 24, 2015. The Agency believes that the extension allows adequate time for interested persons to submit comments without significantly delaying decision making on these important issues.