specific BE recommendations posted on FDA's Web site to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. The guidances, notices, and 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.*

V. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16013 Filed 6–29–15; 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Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings.'' FDA is issuing this draft guidance to describe the Agency's premarket regulatory requirements and the performance testing needed to support liquid barrier claims for gowns intended for use in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 This draft guidance is being issued in light of the public health importance of personal protective equipment in health care settings and the recognition that terminology used to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 This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 31, 2015.

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.

[FR Doc. 2015–16011 Filed 6–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 60-Day Comment Request; Population Assessment of Tobacco and Health Study

AGENCY: National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH), Department of Health and Human Services.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: *To Submit Comments and for Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Kevin P. Conway, Deputy Director, Division of Epidemiology, Services, and Prevention Research, NIDA, NIH, 6001 Executive Boulevard, Room 5185, Rockville, MD 20852; or call non-toll-free number (301) 443–8755 or Email your request, including your address to: *PATHprojectofficer@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection: Cognitive Interviews and Focus Groups for the Population Assessment of Tobacco and Health (PATH) Study (NIDA), 0925–0663–Revision, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a revision request (OMB 0925–0663, expires 11/30/2015) for the Population Assessment of Tobacco and Health (PATH) Study to conduct cognitive interviews and focus groups, to support the development of the Study's questionnaires and other materials. The PATH Study is a national longitudinal cohort study of tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17; the Study conducts annual interviews and collects biospecimens from adults to inform FDA's regulatory actions under the Family Smoking Prevention and Control Act. Cognitive interviews and focus groups are qualitative methods to assess how people interpret, process, retrieve, and respond to phrases, questions, response options, and product images that may be used in the development of the PATH Study's questionnaires and other materials. These methods have previously been used to help the PATH Study improve the comprehensibility of its materials for Study participants, and to increase efficiencies in data collection and reduce duplication and its associated burden on participants and the public.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total annualized burden hours are 2,400.

ESTIMATED ANNUALIZED BURDEN HOURS

Activity name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Completing eligibility screener	Youth	1,200	1	10/60	200
	Adults	2,400	1	10/60	400
Examining concepts to be measured in PATH Study.	Adults	200	1	90/60	300