addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see **ADDRESSES**).

Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients

- Have you received a diagnosis of a functional GI disorder from a health care provider? If so, please state the condition.
- Of all the symptoms that you experience because of your condition, which one to three symptoms have the most significant impact on your life? (Examples may include pain, bloating, constipation, vomiting)
- Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include sleeping through the night, daily hygiene)
  - How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?
- How has your condition and its symptoms changed over time?
  - Do your symptoms come and go or are they ongoing? If so, do you know of anything that worsens your symptoms?
- What worries you most about your condition?

Topic 2: Patients' Perspectives on Current Approaches To Treating Functional GI Disorders

- What are you currently doing to help treat your condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, and other therapies including nondrug therapies such as diet modification.)
  - What specific symptoms do your treatments address?
  - How has your treatment regimen changed over time, and why?
- How well does your current treatment regimen treat the most significant symptoms of your disease?
  - How well do these treatments stop or slow the progression of your condition?
  - How well do these therapies improve your ability to do specific activities that are important to you in your daily life?
  - How well have these treatments worked for you as your condition has changed over time?
- What are the most significant downsides to your current treatments, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, going to the hospital for treatment, restrictions on driving, etc.)
- Assuming there is no complete cure for your condition, what specific things would you look for in an ideal treatment for your condition?

B. Meeting Attendance and Participation

If you wish to attend this meeting, visit *http://pfddfunctionalgidisorders.eventbrite.com.* Please register by May 1, 2015. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Pegah Mariani (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to *PatientFocused@fda.hhs.gov* a brief summary of responses to the topic questions by April 24, 2015. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

III. Comments

Regardless of whether you attend the public meeting, you can submit electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see **ADDRESSES**) by July 13, 2015. 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.*

IV. Transcripts

As soon as a transcript is available, FDA will post it at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm430885.htm.*

Dated: February 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02804 Filed 2–10–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 039

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (''FDA Recognized Consensus Standards''). Specifically, this publication announces the addition of a list of recognized standards that are relevant to safety considerations to mitigate the risks of misconnections with small-bore connectors intended for enteral applications. This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 039'' (''Recognition List Number: 039''), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments concerning this document at any time. See section VI for the effective date of the recognition of standards announced in this document.

ADDRESSES: An electronic copy of Recognition List Number: 039 is available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section V for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 039 modifications and other standards related information.

Submit written requests for single copies of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 039'' to the Division of Industry and Consumer Education, Center for Devices and Radiological Health, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–847–8149.

Submit electronic comments on this document 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: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3632, Silver Spring, MD 20993, 301–796–6287, *standards@cdrh.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled ''Recognition and Use of Consensus Standards.'' The notice described how we would implement our standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.*

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains HTML and PDF versions of the list of FDA Recognized Consensus Standards. Both versions are publicly accessible at the Agency's Internet site. See section V of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Listing of New Entries

In table 1 of this document, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 039. Specifically, this publication announces the addition of a list of recognized standards that are relevant to safety considerations to mitigate the risks of misconnections with small-bore connectors intended for enteral applications. Elsewhere in this issue of the **Federal Register**, we are publishing a notice of availability of the guidance document entitled ''Safety Considerations to Mitigate the Risks of Misconnections With Small-Bore Connectors Intended for Enteral Applications.'' This guidance provides recommendations to manufacturers regarding the expectations for design and testing of small-bore connectors intended for enteral applications (''enteral devices''). FDA is making these recommendations to reduce the risk of unintended connections between enteral and non-enteral devices.

TABLE 1—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
A. General I (Quality Systems/Risk Management)		
5–93	Small-bore connectors for liquids and gases in healthcare applications—Part 3: Connectors for enteral applications.	AAMI/CN3:2014 (PS).
5–94	Small-bore connectors for liquids and gases in healthcare applications—Part 20: Common test methods.	AAMI/CN20:2014 (PS).

[1] All standard titles in this table conform to the style requirements of the respective organizations.

III. List of Recognized Standards

FDA maintains the Agency's current list of FDA recognized consensus standards in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* FDA will incorporate the modifications and revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary. Beginning with Recognition List 033, FDA no longer announces minor revisions to the list of recognized consensus standards such as technical contact person, devices affected, processes affected, Code of Federal Regulations citations, and product codes.

IV. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to *standards@cdrh.fda.gov.* To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

V. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page, *http://www.fda.gov/MedicalDevices,* includes a link to standards-related documents including the guidance and the current list of recognized standards. After publication in the **Federal Register**, this notice announcing ''Modification to the List of

Recognized Standards, Recognition List Number: 039'' will be available *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.*

You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.*

VI. Submission of Comments and Effective Date

Interested persons may submit either electronic comments regarding this document 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. 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.* FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 039. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: February 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02801 Filed 2–10–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Population Assessment of Tobacco and Health (PATH) Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA), 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.

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) The quality, utility, and clarity of the information to be collected; and (4) The approaches used 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.

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: Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Boulevard, Room 5185; 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.

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.

Proposed Collection: Population Assessment of Tobacco and Health (PATH) Study—Third Wave of Data Collection—0925–0664–REVISION—National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a revision request (OMB 0925–0664, Exp. Date 9/30/2016) for the Population Assessment of Tobacco and Health (PATH) Study to conduct the third wave of data collection. The PATH Study is a large national longitudinal cohort study on tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17. The PATH Study conducts annual interviews and collects biospecimens from adults to help inform the development, implementation, and evaluation of tobacco-product regulations by FDA in meeting its mission under the Family Smoking Prevention and Tobacco Control Act (TCA) to regulate tobacco products, including tobacco-product advertising, labeling, marketing, constituents, ingredients, and additives. The longitudinal design of the PATH Study provides it with the capacity to measure and report within-person changes and between-person differences in tobacco product use behaviors and health effects within the cohort over time. These data will help to inform regulatory decisions and actions by FDA and FDA's evaluations of associations between its regulations and tobacco use behaviors and health indicators in the population.

OMB approval is requested for 3 years. There are no capital, operating, or maintenance costs to report. There are no costs to respondents other than their time. The total estimated annualized burden hours are 53,459.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent and instrument	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Adults—Adult respondents at Wave 1 or Wave 2—Extended Interview	25,692	1	1	25,692
Adults—Wave 1 youth respondents who age up to adult cohort at Wave 3—Consent for Extended Interview	2,317	1	4/60	154
Adults—Wave 1 youth respondents who age up to adult cohort at Wave 3—Extended Interview	1,738	1	68/60	1,970
Adults—Wave 1 youth respondents who age up to adult cohort at Wave 3—Consent for Biological Samples	1,738	1	5/60	145
Adults—Biospecimen Collection: Urine	13,703	1	10/60	2,284