''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim—21 CFR 101.82

OMB Control Number 0910–0428—Extension

Section 403(r)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(3)(A)) provides for the use of food label statements characterizing a relationship of any nutrient of the type required to be in the label or labeling of the food to a disease or a health related condition only where that statement meets the requirements of the regulations issued by the Secretary of Health and Human Services to authorize the use of such a health claim. Section 101.82 (21 CFR 101.82) of our regulations authorizes a health claim for food labels about soy protein and the risk of coronary heart disease (CHD). Accordingly, FDA established the previously referenced information collection in support of the regulation. In the **Federal Register** of October 31, 2017 (82 FR 50324), we published a proposed rule to revoke the underlying regulation found at 21 CFR 101.82. We are taking this action based on our review of the totality of publicly available scientific evidence currently available and our tentative conclusion that such evidence does not support our previous determination that there is significant scientific agreement (SSA) among qualified experts for a health claim regarding the relationship between soy protein and reduced risk of coronary heart disease. Upon finalization of the proposed rule the associated information collection requirements under this OMB Control Number will be revoked. Until such time and in accordance with the PRA we retain our currently approved burden estimate for the information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeping	Total annual records	Average burden per recordkeeping	Total hours
101.82(c)(2)(ii)(B)	25	1	25	1	25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based upon our current experience with the use of health claims, we estimate 25 firms market products bearing a soy protein/coronary heart disease health claim and that perhaps one of each firm's products might contain non-soy sources of protein along with soy protein. The records currently required to be retained under § 101.82(c)(2)(ii)(B) are the records, *e.g.,* the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is limited to assembling and retaining the records, which we estimate will take 1 hour annually.

Dated: February 28, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04630 Filed 3–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0756]

Study Design Considerations for Devices Including Digital Health Technologies for Sleep Disordered Breathing in Adults; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Study Design Considerations for Devices including Digital Health Technologies for Sleep Disordered Breathing in Adults.'' The topic to be discussed is the appropriate design of clinical studies to evaluate devices including digital health technologies intended for the diagnosis, monitoring, or treatment of sleep disordered breathing (SDB) in adults. Study design considerations to be discussed include definitions for SDB conditions, inclusion/exclusion criteria for studies of these conditions, use of SDB assessment technologies, controls, and study endpoints.

DATES: The public workshop will be held on April 16, 2018, from 8 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by April 30, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 30, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end April 30, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2018–N–0756 for ''Study Design Considerations for Devices including Digital Health Technologies for Sleep Disordered Breathing in Adults; Public Workshop; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sageev George, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2443, Silver Spring, MD 20993, 301–796–6468, *sageev.george@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Over the past several years, FDA has seen a marked increase in premarket submissions for devices intended for both the diagnosis and treatment of SDB. These include novel technologies for in-home assessment, intra-oral appliances, externally worn devices that generate increased upper airway pressures, passive implants, active implantable devices that stimulate the upper airway neuromusculature, and mobile apps for assessing and monitoring sleep. The large variety of technologies often poses different and challenging questions of safety and effectiveness and differing benefit-risk profiles for these devices. We have planned this workshop to bring together device regulators, clinical experts in sleep medicine, patients, and other stakeholders to discuss these challenges and potential solutions. The goal is to expedite innovation in SDB devices including digital health technologies and make sure that patients have timely access to reasonably safe and effective devices. To this end, we are actively seeking input and participation from several professional societies and patient advocacy groups with interests in the field of SDB.

II. Topics for Discussion at the Public Workshop

The topics to be discussed are the appropriate design of clinical studies to evaluate devices and digital health technologies intended for the diagnosis, monitoring, or treatment of SDB in adults. Study design considerations to be discussed include definitions for SDB conditions, inclusion/exclusion criteria for studies of these conditions, use of SDB assessment technologies (*e.g.,* polysomnography, home sleep studies), controls, and study endpoints.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by April 9, 2018, by 4 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive

confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993–0002, 301–796–5661, email: *Susan.Monahan@fda.hhs.gov,* no later than April 9, 2018.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. The webcast link will be available on the registration web page after April 9, 2018. Organizations are requested to register all participants, but to view using one connection per location.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available approximately 45 days after the public workshop on the internet at *https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.)

Dated: March 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04629 Filed 3–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Information Technology Advisory Committee 2018 Schedule

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), HHS.

ACTION: Notice of the Health Information Technology Advisory Committee 2018 schedule.

SUMMARY: This notice fulfills obligations under section 3002 of the Public Health Service Act (PHSA), as amended by the 21st Century Cures Act. Section 3002(b)(5) of the PHSA, as amended, mandates that the Health Information Technology Advisory Committee shall develop a schedule for the assessment of policy recommendations and the Secretary shall publish such schedule in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Lauren Richie Designated Federal Officer, at *Lauren.Richie@hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 3002 of the Public Health Service Act (PHSA), as amended by the 21st Century Cures Act (Pub. L. 114–255), establishes the Health Information Technology Advisory Committee (HITAC). The HITAC will be governed by the provisions of the Federal Advisory Committee Act (Pub. L. 92–463), as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees. The HITAC, among other things, shall identify priorities for standards adoption and make recommendations to the National Coordinator for Health Information Technology (National Coordinator) on a policy framework to advance an interoperable health information technology infrastructure.

Health Information Technology Advisory Committee Schedule

Section 3002(b)(5) of the PHSA, as amended, provides that the HITAC shall develop a schedule for the assessment of policy recommendations developed by the HITAC and publish the schedule in the **Federal Register**. This schedule addresses the assessment of recommendations outlined in the policy framework recommended by the HITAC to the National Coordinator.

Accordingly, the schedule for the HITAC's assessment of policy recommendations is as follows:

1. Within 90 days of a charge by the National Coordinator for recommendations on a matter, identify the best mechanism to organize itself to develop recommendations, and at a minimum, will:

a. Develop an assessment of what policies, standards, implementation specifications, and certification criteria are currently available to be considered as part of the request;

b. Consider where gaps exist and identify potential organizations that have the capability to address those gaps (*i.e.,* no policy or standard is available or harmonization is required because more than one standard exists) related to the request; and

c. Create a timeline, which may also account for the National Institute of Standards and Technology (NIST) testing, where appropriate, and include dates when the HITAC is expected to issue the recommendation to the National Coordinator.

d. Include an opportunity for public comment during the consideration by the HITAC of the request by the National Coordinator for recommendations on a matter.

2. In responding to the National Coordinator:

a. Approve a timeline to deliver recommendations to the National Coordinator; and

b. Establish a task force to conduct analysis and solicit input, where appropriate, and develop draft recommendations to be considered by the full committee in a timely manner.

3. In collaboration with NIST, annually and through the use of public input, review and publish priorities for the use of health information technology, standards, and implementation specifications to support those priorities.

4. Recommend to the National Coordinator for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. Such recommendations shall include recommended standards, architectures, and software schemes for access to electronic individually identifiable health information across disparate systems including user vetting, authentication, privilege management, and access control.

The topics in which the HITAC is expected to address in FY2018 include, but may not be limited to the target areas as defined in section 3002 of the PHSA, as amended by the 21st Century Cures Act (Pub. L. 114–255), and they include:

1. Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information ;

2. The promotion and protection of privacy and security of health information in health information technology;

3. The facilitation of secure access by an individual to such individual's protected health information; and

4. Any other target area that the HITAC identifies as an appropriate target area to be considered. [42USC § 300jj (b)(2)(B)]