Dated: July 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–15092 Filed 7–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1011]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 15, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0608. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements—21 CFR 111.75(a)(1)(ii)

OMB Control Number 0910–0608—Extension

This information collection supports Agency regulations. The Dietary Supplement Health and Education Act (Pub. L. 103–417) added section 402(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(g)), which provides, in part, that the Secretary of Health and Human Services may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g)(1) of the FD&C Act states that a dietary supplement is adulterated if it has been prepared, packed, or held under the types of conditions that do not meet current good manufacturing practice regulations. Section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives us the authority to issue regulations for the efficient enforcement of the FD&C Act.

Part 111 (21 CFR part 111) establishes the minimum Current Good Manufacturing Practice (CGMP) necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. Section 111.75(a)(1) of our regulations (21 CFR 111.75(a)(1)) establishes a procedure for a petition to request an exemption from 100 percent identity testing of dietary ingredients. Under § 111.75(a)(1)(ii), manufacturers may request an exemption from the requirements set forth in § 111.75(a)(1)(i) when the dietary ingredient is obtained from one or more suppliers identified in the petition. The regulation clarifies that we are willing to consider, on a case-by-case basis, a manufacturer's conclusion, supported by appropriate data and information in the petition submission, that it has developed a system that it would implement as a sound, consistent means of establishing, with no material diminution of assurance compared to the assurance provided by 100 percent identity testing, the identity of the dietary ingredient before use.

Section 111.75(a)(1) reflects our determination that manufacturers that test or examine 100 percent of the incoming dietary ingredients for identity can be assured of the identity of the ingredient. However, we recognize that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, we added to § 111.75(a)(1), an exemption from the requirement of 100 percent identity testing when a manufacturer petitions the Agency for such an exemption to 100 percent identity testing under § 10.30 (21 CFR 10.30) and the Agency grants such exemption. Such a procedure would be consistent with our stated goal, as described in the CGMP final rule, of providing flexibility in the CGMP requirements. Section 111.75(a)(1)(ii) sets forth the information a manufacturer is required to submit in such a petition. The regulation also contains a requirement to ensure that the manufacturer keeps our response to a petition submitted under § 111.75(a)(1)(ii) as a record under § 111.95 (21 CFR 111.95). The collection of information in § 111.95 has been approved under OMB control number 0910–0606.

In the **Federal Register** of April 9, 2018 (83 FR 15159), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received suggesting that ''microbial cultures and probiotics should not be required to go through such a process to ensure exemption from the Agency's 100 percent identity testing requirement,'' but did not suggest a revision to the estimated burden. We appreciate this comment, however, we believe that the current requirements impose minimal information collection while simultaneously ensuring the safety of dietary supplements.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
111.75(a)(1)(ii); Determining whether specifications are met	1	1	1	8	8

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

Since OMB's last approval of the information collection, we have received no petitions. We therefore retain the currently approved estimated burden which assumes no more than one petition will be submitted annually. We further assume it would take respondents 8 hours to prepare the factual and legal information necessary to support a petition for exemption and to prepare the petition, for a total of 8 burden hours annually. These figures are based on our experience with the information collection.

Dated: July 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–15088 Filed 7–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0001]

Scientific Conference: Opioid and Nicotine Use, Dependence, and Recovery—Influences of Sex and Gender; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Office of Women's Health, Center for Drug Evaluation and Research, and Center for Tobacco Products are announcing the following conference entitled ''Scientific Conference: Opioid and Nicotine Use, Dependence, and Recovery—Influences of Sex and Gender.'' The purpose of the conference is to discuss the biological (sex) and sociological (gender) influences on misuse, abuse, and cessation of opioids and tobacco. Researchers, educators, and clinicians may benefit from attending this multidisciplinary review and update on opioid and tobacco.

DATES: The two-day conference will be held on September 27, 2018 (8:30 a.m.–4:00 p.m.) and September 28, 2018 (8:30 a.m.–4:00 p.m.). See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The conference will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503–A), Silver Spring, MD 20993. Entrance for the conference 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*.

FOR FURTHER INFORMATION CONTACT: Gwendolyn Jones, Food and Drug Administration, Bldg. 32, Rm. 2333, 10903 New Hampshire Ave., Silver Spring, MD 20993, *OWH_OandNConf@fda.hhs.gov,* 301–796–9940.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is responsible for protecting the public health by assuring the safety and efficacy of FDA-regulated products. This conference will provide the Agency with further insight into the devastating public health crises caused by pervasive opioid and tobacco use. Drug overdose deaths and opioid-involved deaths continue to increase in the United States. Many of the drug overdose deaths (more than 6 out of 10) involve an opioid. Since 1999, the number of overdose deaths involving opioids (including prescription opioids and heroin) quadrupled. Drug overdose deaths and opioid-involved deaths continue to increase in the United States. Of the 63,632 drug overdose deaths in 2016, 66.4 percent (42,249) involved opioids, with increases across age groups, racial/ethnic groups, urbanization levels, and multiple states. Combustible cigarettes have been identified as the dominant cause of tobacco-related disease and are responsible for more than 20 million premature deaths since the first Surgeon General's report in 1964. Together, opioid and tobacco use are the leading causes of preventable disease and death in the United States, and women are increasingly affected. Sex and gender differences may influence susceptibility to substance abuse, which could have implications for optimal prevention and treatment. Gender influencers also impact public health from a familial and environmental perspective. Researchers, educators, and clinicians must be able to recognize and consider both sex and gender differences to identify and treat women most at risk.

II. Topics for Discussion at the Conference

The conference will include presentations and panel discussions by experts in the field of opioid and tobacco research, professional education, and clinical care on the biological (sex) and sociological (gender) influences on misuse, abuse, and cessation of opioids and tobacco. Each panel discussion will have a Q&A session to respond to questions from in-person attendees.

III. Participating in the Conference

Registration: To register for the Scientific Conference: Opioid and Nicotine Use, Dependence, and Recovery—Influences of Sex and Gender, please visit the following website: *https://www.eventbrite.com/e/scientific-conference-opioid-and-nicotine-use-dependence-and-recovery-influences-of-sex-and-gender-tickets-47087275308*.

Registration is free and in-person seating is limited. The conference will also be available for viewing via webcast. Persons interested in attending or viewing this conference must register online by September 24, 2018, 5:00 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 you need special accommodations due to a disability, please email Gwendolyn Jones at *OWH_OandNConf@fda.hhs.gov* (See **FOR FURTHER INFORMATION CONTACT**) no later than September 24, 2018.

Streaming Webcast of the public meeting: This public meeting will also be webcast and can only be viewed if registered. To register, please go to