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

https://www.eventbrite.com/e/scientific-conference-opioid-and-nicotine-use-dependence-and-recovery-influences-of-sex-and-gender-tickets-47087275308. Registrants will receive confirmation and information about accessing the webcast when they have been accepted. 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.

Dated: July 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–15096 Filed 7–13–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4318]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities

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–NEW and title ''Guidance for Industry on Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.'' 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.

Guidance for Industry on Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities

OMB Control Number—NEW

This information collection supports the Agency guidance document entitled ''Guidance for Industry on Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.''

Under current law, radiopharmaceuticals that are compounded by entities that are not registered with FDA as outsourcing facilities, and radiopharmaceuticals that are repackaged, are subject to all applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) related to drug production. Because Congress explicitly excluded radiopharmaceuticals from section 503A of the FD&C Act (21 U.S.C. 353a) (see section 503A(d)(2)), compounded radiopharmaceuticals are not eligible for the exemptions under section 503A from section 505 of the FD&C Act (21 U.S.C. 355) (concerning new drug approval requirements), section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) (concerning labeling with adequate directions for use), and section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements). In addition, the FD&C Act does not provide an exemption for repackaged radiopharmaceuticals.

FDA developed this guidance document to describe the conditions under which the Agency generally does not intend to take action for violations of sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act when a State-licensed nuclear pharmacy, Federal facility, or other facility that is not an outsourcing facility and that holds a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State compounds or repackages radiopharmaceuticals for human use.

One of the guidance document's conditions is that the compounded radiopharmaceutical is not essentially a copy of an approved radiopharmaceutical. If a compounder intends to rely on a determination from a prescriber that there is a change between the compounded radiopharmaceutical and the comparable approved radiopharmaceutical that produces a clinical difference for an identified individual patient, either the prescribing practitioner or the compounder documents the determination on the prescription or order in writing. This documentation reflects a conversation with the prescribing practitioner, and the compounder maintains records of the prescription or order documenting this determination.

In the **Federal Register** of December 29, 2016 (81 FR 96011), FDA published a notice of availability for the draft guidance, including a 60-day notice soliciting public comment on the information collection recommendations. Several comments were received and are discussed below; however, none of the comments suggested we revise the burden estimate from our 60-day notice.

(Comment 1) One commenter said documentation of a minor deviation from an approved radiopharmaceutical should remain at the facility that performed the minor deviation.

(Response 1) The documentation condition (*i.e.,* documentation of a prescriber's determination that there is a change that produces a clinical difference between the compounded radiopharmaceutical and the comparable FDA-approved radiopharmaceutical for an identified individual patient) does not apply to compounding that consists only of minor deviations as defined in the guidance document (*i.e.,* a change from the approved labeling in radioactivity, volume, or the step-by-step procedures made when compounding the radiopharmaceutical from an FDA-approved drug product in a patient-ready dose). The documentation condition applies to compounding a radiopharmaceutical that involves manipulation other than minor deviations.

(Comment 2) One commenter supports the requirement for notating clinical differences, particularly for documenting both the change to the radiopharmaceutical and the reason that the change is important for the patient.

(Response 2) FDA concurs with this commenter's views about the importance of the documentation.