Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–09463 Filed 5–7–19; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2019–0039]

Vessel Sanitation Program: Annual Program Status Meeting; Request for Comment

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public meeting and request for comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces the 2019 annual Vessel Sanitation Program (VSP) public meeting. The annual meeting serves as a forum for HHS/CDC to update cruise industry representatives and other interested persons on work completed in 2018 and plans for future activities. HHS/CDC is also opening a public docket so that written comments and materials regarding VSP's 2018 and future work may be submitted. The official record of this meeting will remain open through July 26, 2019, so that comments related to the topics discussed at the meeting may be submitted and made part of the record.

DATES: Written comments must be received on or before July 26, 2019.

The meeting will be held from 9:00 a.m. to 4:30 p.m. on June 27, 2019, in the Ballroom at the DoubleTree Grand Hotel Biscayne Bay, 1717 North Bayshore Drive, Miami, FL 33132. Information regarding logistics is available on the VSP website (*www.cdc.gov/nceh/vsp*).

Deadline for Requests for Special Accommodations: Persons wishing to participate in the public meeting who need special accommodations should contact Commander Aimee Treffiletti (*vsp@cdc.gov* or 954–356–6650 or 770–488–3141) by June 25, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0039, by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Vessel Sanitation Program, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS F–58, Atlanta, Georgia 30341.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Commander Aimee Treffiletti, Vessel Sanitation Program, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS F–58, Atlanta, Georgia 30341; phone: 954–356–6650 or 770–488–3141; email: *vsp@cdc.gov*.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to inform the public of VSP's activities to help the cruise industry prevent the introduction and spread of gastrointestinal (GI) illness to U.S. ports from ships under VSP's jurisdiction. Ships under VSP jurisdiction have 13 or more passengers and an itinerary that includes foreign and U.S. ports.

The meeting will include a review of HHS/CDC's public health support activities from 2018, provide perspective on VSP's approach to vessel sanitation, and offer industry the opportunity to provide input regarding industry efforts to exceed VSP requirements. Presentations will clarify the roles and responsibilities of VSP, cruise line public health management, and shipyards constructing cruise ships. Presentations will also include initiatives for improved epidemiologic study of disease outbreaks and strategic approaches to public health risk reduction for 2020 and the future.

Matters To Be Discussed

- VSP year in review: Operational and construction inspections, budget, and vessel sanitation training
- GI illness data and epidemiology projects: VSP review and progress report
- VSP 2018 Operations Manual and Construction Guidelines: Implementation of the new guidance
- Shipyard construction: How to strengthen public health through engineering controls

Meeting Accessibility: The meeting is open to the public, but space is limited to approximately 70 people. Advanced registration is required. Information regarding logistics is available on the VSP website (*www.cdc.gov/nceh/vsp*). Attendees at the annual meeting normally include cruise ship industry officials, private sanitation consultants, and other interested parties.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2019–09393 Filed 5–7–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970–0379]

Submission for OMB Review; Comment Request

Title: ANA Project Outcome Assessment Survey.

Description: The information collected by the Project Outcome Assessment Survey is needed for two main reasons: 1) To collect crucial information required to report on the Administration for Native Americans' (ANA) established Government Performance and Results Act (GPRA) measures, and 2) to properly abide by ANA's congressionally-mandated statute (42 United States Code 2991 *et seq*.) found within the Native American Programs Act of 1974, as amended, which states that ANA will evaluate projects assisted through ANA grant dollars ''including evaluations that describe and measure the impact of such projects, their effectiveness in achieving stated goals, their impact on related programs, and their structure and mechanisms for delivery of services.'' The information collected with this survey will fulfill ANA's statutory requirement and will also serve as an important planning and performance tool for ANA.

Respondents: Tribal Governments, Native American nonprofit organizations, and Tribal Colleges and Universities.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ANA Project Outcome Assessment Survey	85	1	6	510

Estimated Total Annual Burden Hours: 510.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, *Attn:* Desk Officer for the Administration for Children and Families.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–09413 Filed 5–7–19; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2973]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Obtaining Information for Evaluating Nominated Bulk Drug Substances for Use in Compounding Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act

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 June 7, 2019.

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 ''Obtaining Information for Evaluating Nominated Bulk Drug Substances for Use in Compounding Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Clinical Use of Bulk Drug Substances Nominated for Use in Compounding by Outsourcing Facilities OMB Control Number 0910—NEW

This information collection supports Agency-sponsored research. Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b) requires FDA to develop a list of bulk drug substances that may be used in compounding under that section (503B bulks list). Section 503B defines compounding to include the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug. Compounded drugs are not FDA-approved. If the conditions under section 503B are met, drug products compounded by entities known as outsourcing facilities are exempt from the following requirements of the FD&C Act: requirements for FDA approval of drugs in section 505 of the FD&C Act (21 U.S.C. 355), labeling with adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and drug supply chain security requirements under section 582 (21 U.S.C. 360eee-1). One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for these exemptions is that the outsourcing facility may not compound a drug using a bulk drug substance unless (1) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need (''bulks list''); or (2) the substance appears on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) at the time of compounding, distribution, and dispensing.

Many bulk drug substances have been nominated by the public for use in compounding by outsourcing facilities with adequate supporting information for FDA to evaluate them. The substances were nominated to treat a variety of conditions. To inform our evaluation of bulk drug substances for inclusion on the 503B bulks list, we have entered into a research study with the University of Maryland (UMD) Center of Excellence in Regulatory Science and Innovation (CERSI) and the Johns Hopkins University (JHU) CERSI.

FDA intends to use a two-part analysis in evaluating substances nominated for placement on the 503B bulks list to determine whether there is a clinical need. The collaboration with CERSI–UMD and CERSI–JHU pertains to part 2 of the analysis, which applies to bulk drug substances that are not components of FDA-approved drug products, as well as certain bulk drug substances that are components of FDA-approved drug products that have gone through part 1 and warrant further evaluation under part 2 of the analysis. One of the factors that FDA considers under part 2 is ''current and historical use of the substance in compounded drug products, including information about the medical condition(s) that the substance has been used to treat and any references in peer-reviewed medical literature.''

Researchers may use surveys, interviews, focus groups, and other