revenue. The survey will be administered by web or by mail (respondent choice) and it will be directed to the Plant Manager of the cosmetics establishment.

This is a new, one-time data collection. FDA does not plan to collect this data from the cosmetics industry on an ongoing basis.

In the **Federal Register** of July 2, 2018 (83 FR 30940), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received three comments. FDA thanks the commenters for their comments and provides our responses below.

The first comment expressed concern that the collection was voluntary, and a number of manufacturers may not participate, which will not inform FDA of manufacturers who are not observing good manufacturing practices. They also indicated that they feel the survey could help set future standards for the industry. In response to this comment, FDA notes that this survey is being conducted to inform FDA with updated information about the practices and standards employed across the cosmetics industry. With regard to identifying manufacturers who are not observing good manufacturing practices, the survey is structured to provide FDA with anonymized, updated cosmetic industry information, not individual response information about any of its participants.

The second comment addressed specific PRA issues of necessity, burden estimate, quality and utility of the survey, and method of collection. The commenter feels that the survey is not necessary for proper FDA oversight of the industry because this information is already available to FDA through its facility inspections. They also indicated that they had not seen the actual questions on the survey, and therefore felt the burden estimate was not feasible. They suggested that FDA partner with outside sources to assist FDA in gathering information about the industry and thought that web or mail collection was reasonable.

In response to the second comment, FDA noted in the **Federal Register** of July 2, 2018 that FDA has ''not identified in the published literature any systematic, detailed study of the diversity of the practices and standards employed across the cosmetic industry to ensure product quality and safety.'' FDA is conducting this survey to fill this gap in knowledge, and this survey is necessary to achieve this goal. With regard to the survey itself, it is (and has been) available at the FDA Docket assigned to this collection (FDA–2018–N–2027). We agree that the burden is likely greater than 30 minutes, and based on results of our pretest with six individuals, we have increased the burden estimate to 60 minutes. FDA's contractor did consult with industry stakeholders in the development of the survey instrument. Finally, FDA thanks the commenter for their comments and thoughts that our suggested method of web or collection method was reasonable.

The third comment was not related to the PRA and will not be addressed at this time.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Survey Invitation	898	1	898	0.08 (5 minutes)	71.84
Survey	564	1	564	1	564
Total					635.84

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

We will select a sample of 898 establishments. After adjusting for ineligibility (*i.e.*, firms that do not produce cosmetic products and those no longer in operation) and a response rate of 70 percent, we expect 564 completed surveys.

We expect each individual survey invitation to take 5 minutes (0.08 hour) to complete. Multiplying by the 898 establishments that will receive the survey invitation, we estimate the time burden of the survey invitation to be 71.84 hours. Previously, we estimated that the survey would take 30 minutes to complete. However, based on our pretest with six individuals, we now expect each individual survey to take, on average, 60 minutes (1 hour) to complete. Multiplying by the estimated 564 establishments that will complete the survey, we estimate the time burden of the survey to be 564 hours. We estimate the total hourly reporting burden for this collection of information to be 635.84 hours.

Dated: November 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25231 Filed 11–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2012–N–0129]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions; Section 351(k) Biosimilar Applications

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 December 20, 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 0910–0719. 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.

General Licensing Provisions; Section 351(k) Biosimilar Applications

OMB Control Number 0910–0719—Extension

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) amended the Public Health Service Act (PHS Act) and other statutes to create an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. Section 351(k) defines biosimilarity to mean that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that ''there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product'' (see section 351(i)(2) of the PHS Act). A 351(k) application must contain, among other things, information demonstrating that the biological product is biosimilar to a reference product based upon data derived from analytical studies, animal studies, and clinical studies, unless FDA determines, in its discretion, that certain studies are unnecessary in a 351(k) application (see section 351(k)(2) of the PHS Act). To meet the standard for interchangeability, an applicant must provide sufficient information to demonstrate biosimilarity and also to demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch (see section 351(k)(4) of the PHS Act).

Interchangeable products may be substituted for the reference product without the intervention of the prescribing healthcare provider (see section 351(i)(3) of the PHS Act) In estimating the information collection burden for 351(k) biosimilar product applications and interchangeable product applications or supplements, we reviewed the number of 351(k) applications FDA has received in fiscal years 2015, 2016, and 2017, considered responses to a survey of biosimilar sponsors and applicants regarding projected future 351(k) submission volumes, as well as the collection of information regarding the general licensing provisions for biologics license applications under section 351(a) of the PHS Act submitted to OMB (approved under OMB control number 0910–0338).

To submit an application seeking licensure of a proposed biosimilar product under sections 351(k)(2)(A)(i) and (iii) of the PHS Act, the estimated burden hours (FDA believes) would be approximately the same as noted under OMB control number 0910–0338 for a 351(a) application—860 hours. The burden estimates for seeking licensure of a proposed biosimilar product that meets the standards for interchangeability under sections 351(k)(2)(B) and (k)(4) would also be 860 hours per application. FDA believes these estimates are appropriate for 351(k) applications because the paperwork burden for a 351(k) application is expected to be comparable to the paperwork burden for a 351(a) application.

In addition to the collection of information regarding the submission of a 351(k) application for a proposed biosimilar or interchangeable biological product, section 351(l) of the BPCI Act establishes procedures for identifying and resolving patent disputes involving applications submitted under section 351(k) of the PHS Act. The burden estimate for the patent notification provisions under section 351(l)(6)(C) of the BPCI Act are included in table 1 and are based on the estimated number of 351(k) applicants. Based on similar reporting requirements, FDA estimates this notification will take 2 hours.

In the **Federal Register** of July 3, 2018 (83 FR 31152), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

351(k) Applications (42 U.S.C. 262(k))	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
351(k)(2)(A)(i) and 351(k)(2)(A)(iii) Biosimilar Product Applications	4	2.25	9	860	7,740
351(k)(2)(B) and (k)(4) Interchangeable Product Applications or Supplements	2	1	2	860	1,720
351(l)(6)(C) Patent Infringement Notifications	4	2.25	9	2	18
Total					9,478

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

Based on a review of the information collection since our last request for OMB approval, the estimated burden for the information collection reflects an overall increase in total hours and responses. We attribute this adjustment to an increase in the number of submissions received over the last few years and additional interest in the biosimilars program.

Dated: November 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25232 Filed 11–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting for the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC)

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (Secretary) announces a meeting of the Interdepartmental Serious Mental Illness Coordinating Committee (ISMICC).

The ISMICC is open to the public and members of the public can attend the meeting via telephone or webcast only, and not in person. Call-in information will be posted on the ISMICC website prior to the meeting, under the agenda section.

The meeting will include information on federal efforts related to serious mental illness (SMI) and serious emotional disturbance (SED), including federal coordination, strategies, data evaluation, and recommendations for action. Committee members will also discuss federal implementation of ISMICC recommendations.

The ISMICC will conduct five breakout sessions on the following focus areas: Data, Access, Treatment and Recovery, Justice, and Finance.

Committee name: Interdepartmental Serious Mental Illness Coordinating Committee.

Date/Time/Type: December 11, 2018/ 9:00 a.m.–5:00 p.m. (EDT)/OPEN.

ADDRESSES: The meeting will be held at SAMHSA Headquarters, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting can be accessed via webcast at *https://2020archive.1capapp.com/event/ismicc/* or by joining the teleconference at the toll-free, dial-in number at 1–800–369–3143; passcode 4784259.

The public comment section is scheduled for 1:00 p.m. Eastern Daylight Time (EDT), and individuals interested in submitting a comment, must notify the Designated Federal Official, Ms. Pamela Foote, on or before November 26, 2018 via email to: *Pamela.Foote@samhsa.hhs.gov.*

Two minutes will be allotted for each approved public comment as time permits. Written comments received in advance of the meeting will be included in the official record of the meeting.

Substantive meeting information and a roster of Committee members is available at the Committee's website *https://www.samhsa.gov/about-us/advisory-councils/smi-committee.*

SUPPLEMENTARY INFORMATION:

I. Background and Authority

The ISMICC was established on March 15, 2017, in accordance with section 6031 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to report to the Secretary, Congress, and any other relevant federal department or agency on advances in serious mental illness (SMI) and serious emotional disturbance (SED), research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of SMIs, SEDs, and advances in access to services and support for adults with SMI or children with SED. In addition, the ISMICC will evaluate the effect federal programs related to serious mental illness have on public health, including public health outcomes such as (A) rates of suicide, suicide attempts, incidence and prevalence of SMIs, SEDs, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, interaction with the criminal justice system, homelessness, and unemployment; (B) increased rates of employment and enrollment in educational and vocational programs; (C) quality of mental and substance use disorders treatment services; or (D) any other criteria as may be determined by the Secretary. Finally, the ISMICC will make specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with SMI or children with SED. Not later than 1 (one) year after the date of enactment of the 21st Century Cures Act, and 5 (five) years after such date of enactment, the ISMICC shall submit a report to Congress and any other relevant federal department or agency.

II. Membership

This ISMICC consists of federal members listed below or their designees, and non-federal public members.

Federal Membership: Members include, The Secretary of Health and Human Services; The Assistant Secretary for Mental Health and Substance Use; The Attorney General; The Secretary of the Department of Veterans Affairs; The Secretary of the Department of Defense; The Secretary of the Department of Housing and Urban Development; The Secretary of the Department of Education; The Secretary of the Department of Labor; The Administrator of the Centers for Medicare and Medicaid Services; and The Commissioner of the Social Security Administration.

Non-federal Membership: Members include, 14 non-federal public members appointed by the Secretary, representing psychologists, psychiatrists, social workers, peer support specialists, and other providers, patients, family of patients, law enforcement, the judiciary, and leading research, advocacy, or service organizations. The ISMICC is required to meet at least twice per year.

FOR FURTHER INFORMATION CONTACT: Pamela Foote, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, 14E53C, Rockville, MD 20857; telephone: 240–276–1279; email: *pamela.foote@samhsa.hhs.gov.*

Dated: November 15, 2018.

Carlos Castillo,

Committee Management Officer.

[FR Doc. 2018–25310 Filed 11–19–18; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–1044]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0103

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an