approved under OMB control number 0910–0120.

VI. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: June 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16150 Filed 6–30–15; 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 July 31, 2015.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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 Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148) contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), which amends the Public Health Service Act (PHS Act) and establishes an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product (See sections 7001 through 7003 of the Affordable Care Act.)

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 demonstrate interchangeability, an applicant must provide sufficient information to demonstrate biosimilarity and that the biosimilar biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biosimilar 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 biosimilar 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 health care provider. (See section 351(i)(3) of the PHS Act.)

In estimating the information collection burden for 351(k) applications, we reviewed the number of 351(k) applications FDA has received through fiscal year (FY) 2014, 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). For the information collection burden for 351(a) applications, FDA described § 601.2(a) (21 CFR 601.2(a)) as requiring a manufacturer of a biological product to submit an application on forms prescribed for such purpose with accompanying data and information including certain labeling information to FDA for approval to market a product in interstate commerce. FDA also added in the burden estimate the container and package labeling requirements provided under §§ 610.60 through 610.65 (21 CFR 610.60 through 610.65). The estimated hours per response for § 601.2, and §§ 610.60 through 610.65, are 860 hours.

In addition, in submitting a 351(a) application, an applicant completes the Form FDA 356h, ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use.'' The application form serves primarily as a checklist for firms to gather and submit certain information to FDA. The checklist helps to ensure that the application is complete and contains all the necessary information so that delays due to lack of information may be eliminated. The form provides key information to FDA for efficient handling and distribution to the appropriate staff for review. The estimated burden hours for biological product submissions using FDA Form 356h are included under the applicable requirements approved under OMB control number 0910–0338.

To submit an application seeking licensure of a proposed biosimilar product under section 351(k)(2)(A)(i) and (k)(2)(A)(iii) of the PHS Act, FDA believes that the estimated burden hours 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 section 351(k)(2)(B) and (k)(4) would also be 860 hours. Until we gain more experience with biosimilar applications, FDA believes this estimate is

appropriate for 351(k) applications because to determine biosimilarity or interchangeability of a proposed 351(k) product, the application and the information submitted is expected to be comparably as complex and technically demanding as a proposed 351(a) application. FDA may determine, in its discretion, an element required under a 351(k) application to be unnecessary to support licensure of a biosimilar or interchangeable product. In those cases, the number of hours per response may be less than the hours estimated.

A summary of the information collection requirements in the submission of a 351(k) application as described under the BPCI Act follows:

Section 351(k)(2)(A)(i) requires manufactures of 351(k) products to submit an application for FDA review and licensure before marketing a biosimilar product. An application submitted under this section shall include information demonstrating that:

- The biological product is biosimilar to a reference product based upon data derived from analytical studies, animal studies (including toxicity), and a clinical study or studies (including immunogenicity and pharmacokinetics or pharmacodynamics). The Secretary of Health and Human Services (the Secretary) may determine that any of these elements is unnecessary;
- The biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;
- The condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;
- The route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and
- The facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

Section 351(k)(2)(A)(iii) requires the application to include publicly available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent. The application may include any additional information in support of the application, including publicly available information with respect to the reference product or another biological product.

Under section 351(k)(2)(B) and (k)(4), a manufacturer may include information demonstrating that the biological product meets the standards for interchangeability either in the application to show biosimilarity or in a supplement to such an application. The information submitted to meet the standard for interchangeability must show that: (1) The biological product is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient; and (2) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between 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.

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 estimates for the patent provisions under section 351(l)(6)(C) of the BPCI Act are included in table 1 of this document and are based on the estimated number of 351(k) biosimilar respondents. Based on similar reporting requirements, FDA estimates this notification will take 2 hours. A summary of the collection of information requirements under section 351(l)(6)(C) follows:

Not later than 30 days after a complaint from the reference product sponsor is served to a 351(k) applicant in an action for patent infringement described under 351(l)(6), section 351(l)(6)(C) requires that the 351(k) applicant provide the Secretary with notice and a copy of such complaint. The Secretary shall publish in the **Federal Register** notice any complaint received under section 351(l)(6)(C)(i).

In the **Federal Register** of February 3, 2015 (80 FR 5761), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received three comments.

(Comment) One comment requested FDA provide clarity and interpretation regarding the standards for interchangeability (sections 351(k)(2)(B) and (k)(4) of the PHS Act). The comment also sought clarification regarding the timelines and the chosen mode of communication for FDA to convey to the stakeholders any details on an unnecessary element under a 351(k) application.

(Response) FDA expects to issue a draft guidance, ''Considerations in Demonstrating Interchangeability to a Reference Product,'' in 2015. FDA issued a draft guidance, ''Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants,'' in 2013, which provides recommendations to industry on formal meetings between FDA and biosimilar biological product sponsors or applicants.

(Comment) Another comment requested FDA provide clarity on the factors for consideration in assessing whether a proposed biosimilar is highly similar to a reference product to support a demonstration of biosimilarity—specifically, which product quality attributes are considered critical to match (and how much difference is allowed).

(Response) FDA issued the final guidance, ''Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product,'' in April 2015. This final guidance provides further clarification on factors for consideration in assessing whether products are highly similar, including expression system, manufacturing process, impurities, reference product, and reference standards.

(Comment) A third comment supported approval and post-market policies that would allow healthcare practitioners to make informative decisions when treating patients.

(Response) FDA issued the final guidance, ''Scientific Considerations in Demonstrating Biosimilarity to a Reference Product,'' in April 2015. This guidance discusses a stepwise approach to demonstrating biosimilarity, the totality-of-the-evidence approach that FDA will use to review applications for biosimilar products, as well as general scientific principles in conducting comparative structural and functional analyses, animal testing, and clinical studies (including human pharmacokinetic and pharmacodynamic studies, clinical immunogenicity assessment, and comparative clinical studies). The guidance also provides information on postmarketing safety monitoring considerations.

The comment also requested FDA consider adding as part of a biosimilar or interchangeable product's labeling instruction guidance on third party substitution of biosimilars without the knowledge of the healthcare provider. As noted by the comment, these issues

are also subject to state laws and regulations. Under the BPCI Act, a biological product that has been approved as an ''interchangeable'' may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

Based on the number of 351(k) applications FDA received through FY 2014, we estimate that we will receive approximately five 351(k) applications annually. The number of respondents submitting 351(k) applications is based on the number of sponsors submitting 351(k) applications through FY 2014. In making these estimates, FDA has taken into account, among other things, the expiration dates of patents that relate to potential reference products and general market interest in biological products that could be candidates for 351(k) applications.

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	5	1	5	860	4,300
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	5	1	5	2	10
Total					6,030

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

Dated: June 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–16128 Filed 6–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Lists of Designated Primary Medical Care, Mental Health, and Dental Health Professional Shortage Areas

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: This notice advises the public of the published lists of all geographic areas, population groups, and facilities designated as primary medical care, mental health, and dental health professional shortage areas (HPSAs) as of May 29, 2015, available on the Health Resources and Services Administration (HRSA) Web site at *http://www.hrsa.gov/shortage/.* HPSAs are designated or withdrawn by the Secretary of Health and Human Services (HHS) under the authority of section 332 of the Public Health Service (PHS) Act and 42 CFR part 5.

FOR FURTHER INFORMATION CONTACT: Requests for further information on the HPSA designations listed on the HRSA Web site and requests for additional designations, withdrawals, or reapplication for designations should be submitted to Kae Brickerd, Ph.D., Director, Shortage Designation Branch, Division of Policy and Shortage Designation, Bureau of Health Workforce, Health Resources and Services Administration, Mail Stop 11SWH03, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 594–5168.

SUPPLEMENTARY INFORMATION:

Background

Section 332 of the PHS Act, 42 U.S.C. 254e, provides that the Secretary of HHS shall designate HPSAs based on criteria established by regulation. HPSAs are defined in section 332 to include (1) urban and rural geographic areas with shortages of health professionals, (2) population groups with such shortages, and (3) facilities with such shortages. Section 332 further requires that the Secretary annually publish a list of the designated geographic areas, population groups, and facilities. The lists of HPSAs are to be reviewed at least annually and revised as necessary. HRSA's Bureau of Health Workforce (BHW) has the responsibility for designating and updating HPSAs.

Public or private nonprofit entities are eligible to apply for assignment of National Health Service Corps (NHSC) personnel to provide primary care, mental, or dental health services in or to these HPSAs. NHSC health professionals with a service obligation may enter into service agreements to serve only in federally designated HPSAs. Entities with clinical training sites located in HPSAs are eligible to receive priority for certain residency training program grants administered by the BHW. Many other federal programs also utilize HPSA designations. For example, under authorities administered by the Centers for Medicare and Medicaid Services, certain qualified providers in geographic area HPSAs are eligible for increased levels of Medicare reimbursement.

Development of the Designation and Withdrawal Lists

Criteria for designating HPSAs were published as final regulations (42 CFR part 5) in 1980. Criteria then were defined for each of seven health professional types (primary medical care, dental, psychiatric, vision care, podiatric, pharmacy, and veterinary care). The criteria for correctional facility HPSAs were revised and published on March 2, 1989 (54 FR 8735). The criteria for psychiatric HPSAs were expanded to mental health HPSAs on January 22, 1992 (57 FR 2473). Currently funded PHS Act programs use only the primary medical care, mental health, or dental HPSA designations.

Individual requests for designation or withdrawal of a particular geographic area, population group, or a facility as a HPSA are received and reviewed continuously by BHW. The majority of the requests come from the Primary Care Offices (PCO) in the State Health Departments, who have access to the on-line application and review system. Requests that come from other sources are referred to the PCOs for their review and concurrence. In addition, interested parties, including the Governor, the State Primary Care Association and state professional associations are notified of each request submitted for their comments and recommendations.