

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 BURDEN¹

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.
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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 HPSAs are designated or withdrawn by the Secretary of Health and Human Services (HHS) under the authority of section 332 of the Public Health Service (PHS) Act and 42 CFR part 5.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.

Annually, lists of designated HPSAs are made available to all PCOs, state medical and dental societies and others, with a request to review and update the data on which the designations are based. Emphasis is placed on updating those designations that are more than 3 years old or where significant changes relevant to the designation criteria have occurred.

Recommendations for possible additions, continuations, revisions, or withdrawals from a HPSA list are reviewed by BHW, and the review findings are provided by letter to the agency or individual requesting action or providing data, with copies to other interested organizations and individuals. These letters constitute the official notice of designation as a HPSA, rejection of recommendations for HPSA designation, revision of a HPSA designation, and/or advance notice of pending withdrawals from the HPSA list. Designations (or revisions of designations) are effective as of the date on the notification letter from BHW. Proposed withdrawals become effective only after interested parties in the area affected have been afforded the opportunity to submit additional information to BHW in support of its continued or revised designation. If no new data are submitted, or if BHW review confirms the proposed withdrawal, the withdrawal becomes effective upon publication of the lists of designated HPSAs in the **Federal Register**. In addition, lists of HPSAs are updated daily on the HRSA Web site at <http://www.hrsa.gov/shortage/>, so that interested parties can access the most accurate and timely information.

Publication and Format of Lists

Due to the large volume of designations, a printed version of the list is no longer distributed. This notice serves to inform the public of the availability of the complete listings of designated HPSA on the HRSA Web site. The three lists (primary medical care, mental health, and dental) of designated HPSAs are available at a link on the HRSA Web site at <http://www.hrsa.gov/shortage/> and include a snapshot of all geographic areas, population groups, and facilities that were designated HPSAs as of May 29, 2015. This notice incorporates the most recent annual reviews of designated HPSAs and supersedes the HPSA lists published in the **Federal Register** on June 25, 2014 (**Federal Register**/Vol. 79, No. 122/Wednesday, June 25, 2014/ Notices 36075). The lists also include automatic facility HPSAs, designated as a result of the Health Care Safety Net Amendments of 2002 (Pub. L. 107-251),

not subject to update requirements. Each list of designated HPSAs (primary medical care, mental health, and dental) is arranged by state. Within each state, the list is presented by county. If only a portion (or portions) of a county is (are) designated, or if the county is part of a larger designated service area, or if a population group residing in the county or a facility located in the county has been designated, the name of the service area, population group, or facility involved is listed under the county name. Counties that have a whole county geographic HPSA are indicated by the "Entire county HPSA" notation following the county name. Further details on the snapshot of HPSAs listed can be found on the HRSA Web site at <http://www.hrsa.gov/shortage/>.

In addition to the specific listings included in this notice, all Indian Tribes that meet the definition of such Tribes in the Indian Health Care Improvement Act of 1976, 25 U.S.C. 1603(d), are automatically designated as population groups with primary medical care and dental health professional shortages. The Health Care Safety Net Amendments of 2002 also made the following entities eligible for automatic facility HPSA designations: All federally qualified health centers (FQHCs) and rural health clinics that offer services regardless of ability to pay. These entities include: FQHCs funded under section 330 of the PHS Act, FQHC Look-Alikes, and Tribal and urban Indian clinics operating under the Indian Self-Determination and Education Act of 1975 (25 U.S.C. 450) or the Indian Health Care Improvement Act. Many, but not all, of these entities are included on this listing. Exclusion from this list does not exclude them from HPSA designation; any facilities eligible for automatic designation will be included in the database as they are identified.

Future Updates of Lists of Designated HPSAs

The lists of HPSAs on the HRSA Web site consist of all those that were designated as of May 29, 2015. It should be noted that HPSAs are currently updated on an ongoing basis based on the identification of new areas, population groups, facilities, and sites that meet the eligibility criteria or that no longer meet eligibility criteria and/or are being replaced by another type of designation. As such, additional HPSAs may have been designated by letter since that date. The appropriate agencies and individuals have been or will be notified of these actions by letter. These newly designated HPSAs will be included in the next publication

of the HPSA list and are currently included in the daily updates posted on the HRSA Web site at <http://www.hrsa.gov/shortage/find.html>.

Any designated HPSA listed on the HRSA Web site is subject to withdrawal from designation if new information received and confirmed by HRSA indicates that the relevant data for the area involved have significantly changed since its designation. The effective date of such a withdrawal will be the next publication of a notice regarding this list in the **Federal Register**.

All requests for new designations, updates, or withdrawals should be based on the relevant criteria in regulations published at 42 CFR part 5.

Electronic Access Address

The complete list of HPSAs designated as of May 29, 2015, are available on the HRSA Web site at <http://www.hrsa.gov/shortage/>. Frequently updated information on HPSAs is also available at <http://datawarehouse.hrsa.gov>.

Dated: June 25, 2015.

James Macrae,
Acting Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than July 31, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_