

utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Survey of Current Manufacturing Practices for the Cosmetics Industry—OMB Control Number 0910—New**

FDA has the responsibility to protect public health and, as part of this broad mandate, oversees the safety of the nation’s cosmetic products. The Federal Food, Drug, and Cosmetic Act (FD&C Act) prohibits the introduction into interstate commerce of any cosmetic that is adulterated or misbranded.

The FD&C Act defines cosmetics as articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial

makeup, cleansing shampoos, permanent waves, hair colors, deodorants, and tattoo inks, as well as any substance intended for use as a component of a cosmetic product. Some cosmetic products are also regulated as drugs.

As with other commodities FDA regulates, the safety of cosmetic products can be ensured in part through a manufacturer’s approach to the management of cosmetic quality. To date, 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. This study is intended to fill this gap. FDA proposes to conduct a voluntary survey of cosmetics establishments to identify the current quality management and safety practices in the cosmetic industry.

The survey instrument will collect data, on a voluntary basis, from cosmetic product manufacturers on the following topics:

- **Written Procedures and Documentation**—including written procedures and records for manufacturing involving personnel, raw materials, processing, cleaning, maintenance, finished products, and training.

- **Buildings and Equipment**—including facility space, pest control, practices ensuring the cleanliness and sanitation, water usage and treatment, and the proper functioning and operation of equipment.

- **Materials and Manufacturing**—including practices for inventory management, labeling and storage of raw materials, closures, and in process materials; and in process standard operating procedures.

- **Quality Control/Product Testing**—including the scope of the quality control unit, laboratory testing, dealing with rejected or returned products and complaints, and corrective actions.

In addition, FDA will obtain the characteristics of surveyed establishments such as the types of cosmetics produced, published standards and guidelines followed, the number of employees, the volume of production, and the approximate 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

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	0.5 (30 minutes) .....	282.00
Total .....					353.84

<sup>1</sup> 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. We expect each individual survey to take 30 minutes (0.5 hour) to complete. Multiplying by the estimated 564 establishments that will complete the survey, we estimate the time burden of the survey to be 282 hours. We estimate the total hourly reporting

burden for this collection of information to be 353.84 hours.

Dated: June 26, 2018.  
**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 (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** This notice informs the public of the availability of the complete 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 1, 2018. The lists are available on HRSA's HPSAFind website.

**ADDRESSES:** Complete lists of HPSAs designated as of May 1, 2018, are available on the HPSAFind website at <https://datawarehouse.hrsa.gov/tools/analyzers/hpsafind.aspx>. Frequently updated information on HPSAs is available at <http://datawarehouse.hrsa.gov>. Information on shortage designations is available at <https://bhw.hrsa.gov/shortage-designation>.

**FOR FURTHER INFORMATION CONTACT:** For further information on the HPSA designations listed on the HPSAFind website or to request additional designation, withdrawal, or reapplication for designation, please contact Melissa Ryan, Acting Director, Division of Policy and Shortage Designation, Bureau of Health Workforce, HRSA, 11SWH03, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 594-5168 or [MRyan@hrsa.gov](mailto:MRyan@hrsa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

Section 332 of the Public Health Service (PHS) Act, 42 U.S.C. 254e, provides that the Secretary 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 lists of the designated geographic areas, population groups, and facilities. The lists of HPSAs are to be reviewed at least annually and revised as necessary.

Final regulations (42 CFR part 5) were published in 1980 that include the criteria for designating HPSAs. Criteria were defined for 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.

HPSA designation offers access to potential federal assistance. Public or private nonprofit entities are eligible to apply for assignment of National Health Service Corps (NHSC) personnel to provide primary medical care, mental

health, or dental health services in or to these HPSAs. NHSC health professionals enter into service agreements to serve 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 HRSA's Bureau of Health Workforce (BHW). 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.

##### Content and Format of Lists

The three lists of designated HPSAs are available on the HPSAFind website and include a snapshot of all geographic areas, population groups, and facilities that were designated HPSAs as of May 1, 2018. This notice incorporates the most recent annual reviews of designated HPSAs and supersedes the HPSA lists published in the **Federal Register** on June 26, 2017 (**Federal Register**/Vol. 82, No. 121/Monday, June 26, 2017/Notices 28863).

In addition, 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. Further, the Health Care Safety Net Amendments of 2002 provides eligibility for automatic facility HPSA designations for all federally qualified health centers (FQHCs) and rural health clinics that offer services regardless of ability to pay. Specifically, 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. Absence from this list does not exclude them from HPSA designation; facilities eligible for automatic designation are included in the database when they are identified.

Each list of designated HPSAs 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, a county is part of a larger designated service area, or a population group residing in a 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. A county that has a whole county geographic HPSA is indicated by the phrase "Entire county HPSA" following the county name.

##### Development of the Designation and Withdrawal Lists

Requests for designation or withdrawal of a particular geographic area, population group, or a facility as a HPSA are received continuously by BHW. Under a Cooperative Agreement between HRSA and the 54 state and territorial Primary Care Offices (PCOs), PCOs conduct needs assessments and submit the majority of the applications to HRSA to designate areas as HPSAs. BHW refers requests that come from other sources to PCOs for review. In addition, interested parties, including Governors, State Primary Care Associations, and state professional associations, are notified of requests so that they may submit their comments and recommendations.

BHW reviews each recommendation for possible addition, continuation, revision, or withdrawal. Following review, BHW notifies the appropriate agency, individuals, and interested organizations of each designation of a HPSA, rejection of recommendation 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 from BHW and are updated daily on the HPSAFind website. The effective date of a withdrawal will be the next publication of a notice regarding the list in the **Federal Register**.

Dated: June 26, 2018.

**George Sigounas,**  
*Administrator.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990—new]

##### Agency Information Collection Request; 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.  
**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.