This guidance recommends an approach to identifying EDDOs, provides examples of EDDOs for specific types of devices, and describes the information and data related to EDDOs that is provided in an application or submission. Examples of products that are within the scope of this guidance include syringes, injectors (*e.g.,* autoinjector, on body injector), infusion products (*e.g.,* infusion pumps), nasal sprays, inhalers, nebulizers, and vaginal systems.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drug applications have been approved under OMB control number 0910–0014 and the collections of information in 21 CFR part 812 for investigational device exemptions have been approved under OMB control number 0910–0078. The collections of information in 21 CFR part 314 for new drug applications and abbreviated new drug applications, including the collections of information contained in the guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' have been approved under OMB control number 0910–0001. The collections of information in 21 CFR parts 601 and 610 for biologics license applications have been approved under OMB control number 0910–0338. The collections of information in section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) have been approved under OMB control number 0910–0718. The collections of information in 21 CFR part 814 for premarket approval applications have been approved under OMB control number 0910–0231. The collections of information in section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), subpart E for 510(k) notifications, have been approved under OMB control number 0910–0120. The collections of information in 21 CFR 860, subpart D for De Novo classifications have been approved under OMB control number 0910–0844. The collections of information in 21 CFR part 211 for current good manufacturing practice for finished pharmaceuticals have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 820 for the quality system regulation have been approved under OMB control number 0910–0073. The collections of information in 21 CFR part 807, subpart E for premarket notification have been approved under OMB control number 0910–0120. The collections of information for meetings related to generic drug development have been approved under OMB control number 0910–0727. The collections of information in the guidance for industry and FDA staff entitled ''Requests for Feedback on Medical Device Submissions: The Q-Submission Program and Meetings with the Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/combination-products/guidance-regulatory-information/combination-products-guidance-documents, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 25, 2024.

Lauren K. Roth,

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.

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, dental health, and mental health professional shortage areas (HPSAs) in a designated status as of April 15, 2024. The lists are available on the shortage area topic page on HRSA's *data.hrsa.gov* website. All currently designated HPSAs remain designated until final lists are published later this fall. HPSA designations that are currently proposed for withdrawal will remain in this status until the publication of the HPSA **Federal Register** notice on or before November 1, 2024. HPSAs proposed for withdraw will be re-evaluated before final publication if additional information is made available to HPSA by states. If these HPSAs do not meet the requirements for designation at the time of the publication of the HPSA **Federal Register** on or before November 1, 2024, they will be withdrawn.

ADDRESSES: Complete lists of currently designated HPSAs as of April 15, 2024, and include those proposed for withdraw, are available on the website at *https://data.hrsa.gov/tools/health-workforce/shortage-areas/frn.* Frequently updated information on HPSAs is available at *https://data.hrsa.gov/topics/health-workforce/health-workforce-shortage-areas.* Information on shortage designations is available at *https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation.*

FOR FURTHER INFORMATION CONTACT: For further information on the HPSA designations listed on the website or to request additional designation, withdrawal, or reapplication for designation, please contact Matthew Patterson, Acting Branch Chief, Shortage Designation Branch, Division of Policy and Shortage Designation, Bureau of Health Workforce (BHW), HRSA, 5600 Fishers Lane, Rockville, Maryland 20857, *sdb@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 on November 17, 1980 (45 FR 75996) 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 published on October 29, 1987 (52 FR 41594) and revised 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 the primary medical care, mental health, or dental HPSA or relevant sub-score designations such as Maternity Care Target Areas.

HPSA designation offers access to potential federal assistance. Public or private nonprofit entities are eligible to apply for assignment of National Health Service Corps personnel to provide primary medical care, mental health, or dental health services in or to these HPSAs. National Health Service Corps 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 & 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 HRSA Data Warehouse shortage area topic web page, including those proposed for withdraw, and include a snapshot of all geographic areas, population groups, and facilities that were designated HPSAs as of April 15, 2024. This notice incorporates the most recent annual reviews of designated HPSAs and supersedes the HPSA lists published in the **Federal Register** on January 2, 2024 (FR/Vol. 89, No. 1, Tuesday, January 2, 2024/Document Number 2023–28844). The proposed for withdraw HPSAs will remain in that status until the lists are finalized this fall. States have the opportunity to provide additional information as part of the review of proposed for withdraw HPSAs prior to the lists being finalized this fall.

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, 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 or population group HPSA is indicated by the phrase ''County'' following the county name.

Development of the Designation and Withdrawal Lists

Requests for designation or withdrawal of a particular geographic area, population group, or 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 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 HRSA Data Warehouse website. The effective date of a withdrawal will be the next publication of a notice regarding the list of designated HPSAs in the **Federal Register**.

Carole Johnson,

Administrator.

[FR Doc. 2024–14477 Filed 6–28–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information (RFI): Inviting Comments and Suggestions on an ODS Strategic Plan 2025–2029: A Blueprint for a Coordinated Dietary Supplement Research Agenda at NIH

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

SUMMARY: The National Institutes of Health (NIH), Office of Dietary Supplements (ODS) is continuing to use a structured planning process to develop its five-year strategic plans. After a new director joined ODS in July 2023 a new strategic plan for 2025–2029 was developed titled ''A Blueprint for a Coordinated Dietary Supplement Research Agenda at NIH.'' ODS is committed to engaging its partners and other interested parties including representatives of the scientific community, industry, other federal agencies, policymakers, and the public in the strategic planning process by soliciting their comments on the draft ODS Strategic Plan for Fiscal Years (CY) 2025–2029.

DATES: The RFI is open for public comment for a period of 60 days. To ensure consideration, comments must be submitted by August 30, 2024.

ADDRESSES: All comments must be submitted electronically to *ODSplan@od.nih.gov.* You will receive an electronic confirmation acknowledging receipt of your response.

FOR FURTHER INFORMATION CONTACT: Barbara Cohen, Ph.D., at *ODSplan@od.nih.gov* or (301) 435–2920.

SUPPLEMENTARY INFORMATION: This notice is in accordance with the 21st Century Cures Act, wherein NIH institutes are required to regularly update their strategic plans. The purpose of the CY 2025–2029 ODS Strategic Plan (*https://ods.od.nih.gov/*