

labeling a statement provided for in section 403(r)(6) of the FD&C Act. In accordance with these requirements, submissions must include: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) the signature of a responsible individual or the person who can certify the accuracy of the information presented, and who must certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Our electronic form (Form FDA 3955) allows respondents to the information collection to electronically submit notifications to FDA via the Food Applications Regulatory Management (FARM) system. Firms that prefer to submit a paper notification in a format of their own choosing will still have the option to do so; however, Form FDA 3955 prompts respondents to include certain elements in their structure/function claim notification (SFCN) described in § 101.93 in a standard electronic format and helps respondents organize their SFCN to include only the information needed for our review of the claim. Note that the SFCN, whether electronic or paper, is used for all claims made pursuant to section 403(r)(6) of the FD&C Act, including nutrient deficiency claims and general

well-being claims in addition to structure/function claims. The electronic form, and any optional elements prepared as attachments to the form (e.g., label), can be submitted in electronic format via FARM. Submissions of SFCNs will continue to be allowed in paper format. We use this information to evaluate whether statements made for dietary ingredients or dietary supplements are permissible under section 403(r)(6) of the FD&C Act.

#### *Description of Respondents:*

Respondents to this collection of information include manufacturers, packers, or distributors of dietary supplements that bear section 403(r)(6) of the FD&C Act statements on their labels or labeling.

We estimate the burden of this collection of information as follows:

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

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
101.93 .....	3,690	1	3,690	0.75 (45 minutes) .....	2,768

<sup>1</sup> 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, we have made no adjustments to our burden estimate. This estimate is based on our experience with this information collection and the number of notifications received in the past 3 years, which has remained constant.

Dated: November 26, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Solicitation of Nominations for Membership To Serve on the National Advisory Council on Migrant Health

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Request for nominations.

**SUMMARY:** HRSA is seeking nominations of qualified candidates to be considered for appointment as members of the National Advisory Council on Migrant Health (NACMH or advisory committee). The NACMH advises,

consults with, and makes recommendations to the HHS Secretary concerning the organization, operation, selection, and funding of Migrant Health Centers (MHCs) and other entities under grants and contracts under the Public Health Service (PHS) Act. HRSA is seeking nominations to fill seven positions on the NACMH.

**DATES:** HRSA will receive written nominations for NACMH membership on a continuous basis.

**ADDRESSES:** Nomination packages must be submitted in hard copy to the Designated Federal Official (DFO), NACMH, Strategic Initiatives Division, Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 16N38B, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** All requests for information regarding NACMH nominations should be sent via email to Esther Paul, DFO, NACMH, HRSA at [hrsabphcoppdnacmh@hrsa.gov](mailto:hrsabphcoppdnacmh@hrsa.gov) or 301-594-4300. The NACMH charter and list of current membership are available on the NACMH website at <https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html>.

**SUPPLEMENTARY INFORMATION:** NACMH was established and authorized under section 217 of the PHS Act (42 U.S.C. 218) to advise, consult with, and make recommendations to the HHS Secretary

concerning the organization, operation, selection, and funding of MHCs and other entities under grants and contracts under section 330(g) of the PHS Act (42 U.S.C. 254b(g)). The NACMH meets twice each calendar year, or at the discretion of the DFO in consultation with the Chair.

**Nominations:** HRSA is requesting nominations for voting members to serve as Special Government Employees (SGEs) on the NACMH to fill seven open positions. Specifically, HRSA is requesting nominations for the following positions: Board Member (three nominees), Board Member/Patient (three nominees), and Administrator Provider (one nominee). The Board Member nominees must be members or members-elect of a governing board of an organization receiving funding under section 330(g) of the PHS Act. The Board Member/Patient nominees must also be patients of the health centers that they represent. Additionally, Board Member nominees must be familiar with the delivery of primary health care to migratory and seasonal agricultural workers (MSAWs) and their families. The Administrator/Provider nominee must be qualified by training and experience in the medical sciences or in the administration of health programs for MSAWs and their families. Another individual or organization may nominate an interested applicant.

The HHS Secretary appoints NACMH members with the expertise needed to fulfill the duties of the advisory committee. The membership requirements set forth under section 217 of the PHS Act (42 U.S.C. 218) require that the NACMH consist of 15 members, at least 12 of whom shall be members of the governing boards of MHCs or other entities assisted under section 330(g) of the PHS Act (42 U.S.C. 254b(g)). Of these 12 board members, at least nine shall be individuals who are MHC patients and familiar with the delivery of health care to MSAWs. The remaining three NACMH members shall be individuals qualified by training and experience in the medical sciences or in the administration of health programs. New members filling a vacancy occurring prior to term expiration may serve only for the remainder of such term. Members may serve after term expiration until their successors take office, but no longer than 120 days. Nominees must reside in the United States, and international travel cannot be funded.

Individuals selected for appointment to the NACMH will be invited to serve for up to 4 years. Members appointed as SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending NACMH meetings and/or conducting other business on behalf of the NACMH, as authorized by 5 U.S.C. 5703 for persons employed intermittently in government service.

The following information must be included in the package of materials submitted for each individual nominated for consideration: (1) NACMH nomination form, which can be requested by contacting the DFO at the email provided above; (2) three letters of reference; (3) a statement of prior service on the NACMH; and (4) a current copy of the nominee's curriculum vitae. Nomination packages may be submitted directly by the individual being nominated or by the person/organization recommending the candidate.

HHS endeavors to ensure that NACMH membership is fairly balanced in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, and ethnic and minority groups, as well as individuals with disabilities, are considered for membership. Appointments shall be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, or cultural, religious, or socioeconomic status.

Individuals under consideration for appointment will be required to provide

detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is required in order for HRSA ethics officials to determine whether there is a potential conflict of interest between the SGE's public duties as a member of the NACMH and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations, and to identify any required remedial action needed to address the potential conflict.

*Authority:* NACMH is authorized by section 217 of the PHS Act, Title 42 U.S.C. 218, and established by the HHS Secretary. It is governed by the Federal Advisory Committee Act (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

**Maria G. Button,**

*Director, Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine or Oral Fluid (Mandatory Guidelines).

#### FOR FURTHER INFORMATION CONTACT:

Anastasia Donovan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240-276-2600 (voice); [Anastasia.Donovan@samhsa.hhs.gov](mailto:Anastasia.Donovan@samhsa.hhs.gov) (email).

**SUPPLEMENTARY INFORMATION:** In accordance with Section 9.19 of the Mandatory Guidelines, a notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked,

the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at <https://www.samhsa.gov/workplace/resources/drug-testing/certified-lab-list>.

The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020.

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using Urine and/or