is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: A State Plan is a required comprehensive narrative description of the nature and scope of a State's or Replacement Designee's (RD) Refugee Resettlement Program and provides assurances that the program will be administered in conformity with the specific requirements stipulated in 45 CFR 400.4–400.9. The State Plan must include all applicable State or RD procedures, designations, and certifications for each requirement as well as supporting documentation. The plan assures ORR that the State or RD is capable of administering refugee assistance and coordinating employment and other social services for eligible caseloads in conformity with specific requirements.

ORR proposes the following changes to the previously approved State Plan for Grants to States for Refugee Resettlement:

- streamlining/formatting multiple sections of the form, including technical corrections
- enhancing requirements for collaboration and engagement and expanding the non-discrimination aspects
- standardizing sections of the template related to health to reduce burden by clarifying text and removing duplicative parts
- streamlining sections related to the unaccompanied children to reduce burden by providing better options for responses and selections and by removing unnecessary and confusing text to ensure consistency regarding assurances

Respondents: State agencies and RDs under 45 CFR 400.301(c) administering or supervising the administration of programs.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
State Plan for Grants to States for Refugee Resettlement	59	1	18	1,062

Authority: 8 U.S.C. 1522 of the Immigration and Nationality Act (the Act) [title IV, sec. 412 of the Act] for each State agency requesting Federal funding for refugee resettlement under 8 U.S.C. 524 [title IV, sec. 414 of the Act]

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–00704 Filed 1–16–24; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2780]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Submit written comments (including recommendations) on the collection of information by February 16, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0330. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Premarket Notification for a New Dietary Ingredient—21 CFR 190.6

OMB Control Number 0910–0330—Revision

This information collection supports Agency regulation, guidance, and associated Form FDA 3880. Under section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350b(a)(2)), the manufacturer or distributor of a new dietary ingredient (NDI) or a dietary supplement that contains the NDI, must submit an NDI notification (NDIN) to FDA (as delegate for the Secretary of Health and Human Services) at least 75 days before introducing the product into interstate commerce, unless the NDI and any other dietary ingredients in the dietary supplement ''have been present in the food supply as an article used for food in a form in which the food has not been chemically altered'' (21 U.S.C. 350b(a)(1)).

The notification must contain the information, including any citation to published articles, which provides the basis on which the manufacturer or distributor of the NDI or dietary supplement (the notifier) has concluded that the dietary supplement containing the NDI will reasonably be expected to be safe (21 U.S.C. 350b(a)(2)). If the required premarket notification is not submitted to FDA, section 413(a) of the

FD&C Act provides that the dietary supplement containing the NDI is deemed to be adulterated under section 402(f) of the FD&C Act (21 U.S.C. 342(f)). Even if the notification is submitted as required, the dietary supplement containing the NDI is adulterated under section 402(f) of the FD&C Act unless there is a history of use or other evidence of safety establishing that the NDI, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe.

Section 190.6 (21 CFR 190.6) specifies the information a notifier must include in its NDIN and establishes the administrative procedures for these notifications. Section 190.6(a) requires each manufacturer or distributor of an NDI, or of a dietary supplement containing an NDI, to submit to the Center for Food Safety and Applied Nutrition's (CFSAN's) Office of Dietary Supplement Programs (ODSP) notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6(b) requires that the notification include the following: (1) the complete name and address of the manufacturer or distributor, (2) the name of the NDI, (3) a description of the dietary supplement(s) that contain the NDI, including the level of the new dietary ingredient in the dietary supplement and the dietary supplement's conditions of use, (4) the history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling of the dietary supplement, and (5) the signature of a responsible person designated by the manufacturer or distributor.

These NDIN requirements are designed to enable us to monitor the introduction into the marketplace of NDIs and dietary supplements that contain NDIs in order to protect consumers from ingredients and products whose safety is unknown. We use the information collected in the NDINs to evaluate more efficiently the safety of NDIs in dietary supplements and to support regulatory action against ingredients and products that are potentially unsafe.

FDA developed guidance to further assist industry with NDINs. In the **Federal Register** of July 5, 2011 (76 FR 39111), we announced the availability of a draft guidance for industry entitled ''Dietary Supplements: New Dietary Ingredient Notifications and Related Issues'' (the 2011 draft guidance). We gave interested parties an opportunity to submit comments on the substance of the guidance by October 3, 2011. In the **Federal Register** of September 9, 2011 (76 FR 55927), we extended the comment period to December 2, 2011. We received numerous comments on the 2011 draft guidance. Based on those comments and our meetings with industry and other stakeholders, we revised the 2011 draft guidance. In the **Federal Register** of August 12, 2016 (81 FR 53486), we announced the availability of a revised draft guidance for industry with the same title (the 2016 revised draft guidance) that supersedes the 2011 draft guidance (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-new-dietary-ingredient-notifications-and-related-issues*). We gave interested parties another opportunity to submit comments on the substance of the guidance by October 11, 2016. In the **Federal Register** of October 4, 2016 (81 FR 68434), we extended the comment period to December 12, 2016. It is with this notice that we solicit comments on the information collection in the guidance.

The 2016 revised draft guidance, when finalized, is intended to provide instruction and further assist industry in deciding when a premarket safety notification for a dietary supplement containing an NDI is necessary and in preparing an NDIN. The draft guidance discusses in question-and-answer format FDA's views on what qualifies as an NDI, when an NDIN is required, the types of data and information that manufacturers and distributors should consider when they evaluate the safety of a dietary supplement containing an NDI, and what should be included in an NDIN as well as other topics. We intend to divide the 2016 revised draft guidance into discrete sections for ease of use, consistent with stakeholder requests (including from industry) submitted in the form of comments to the docket for the draft guidance, and issue a series of several guidances. These guidances will reflect, among other things, public comments submitted to the docket in response to the 2011 draft guidance and the 2016 revised draft guidance. Sections of the 2016 revised draft guidance that FDA is prioritizing to issue at this time address administrative procedures, identity, safety, and master files. Per our standard process, FDA will announce guidance documents we plan to issue within a calendar year via our FDA Foods Program Guidance Agenda, available at *https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/foods-program-guidance-under-development.* The following sections discuss the various topics related to NDINs, all of which were previously referenced or discussed in the 2016 revised draft guidance.

1. Administrative Procedures

The recommendations found in section V, NDI Notification Procedures and Timeframes, of the 2016 revised draft guidance and certain recommendations in section IV.C., Other Questions About When an NDI Notification Is Necessary, provide instruction for certain ways manufacturers and distributors can reduce the number of NDINs they must file and provide some clarification with regard to when data and information from a previous NDIN may be used in a notification. We recommend that certain information should be provided in list form for ease of reference and to help ensure completeness.

Certain recommendations found in the 2016 revised draft guidance, section IV.C., Determining Whether a New Dietary Ingredient (NDI) Notification Is Required; Other Questions About When an NDI Notification Is Necessary, discusses information that should be included if referring to non-public information from a previous notification. Such information to include with a notification could involve written authorization to reference information from another firm. The option to reference certain information from a previous notification should reduce notifiers' burden for preparing and submitting identity, manufacturing, and safety information.

We encourage manufacturers or distributors of NDIs to submit their NDINs electronically via the CFSAN Online Submission Module (COSM). Although we encourage electronic submission, notifiers also have the option of submitting a paper NDIN for us to review. The recommendations found in the 2016 revised draft guidance, section V, Recommended Template for Organizing an NDI Notification, recommend that information in a paper NDIN should be organized in a specific manner, and that some information should be provided in list form, for ease of reference and to ensure completeness. Doing so will help notifiers provide a complete, well-organized NDIN, which should facilitate an efficient and timely FDA review.

These sections of the 2016 revised draft guidance provide instruction and help dietary supplement manufacturers and distributors understand what to

expect when submitting an NDIN and enhance industry's ability to submit a complete notification that FDA can efficiently review.

2. Identity Information About the NDI and the Dietary Supplement

Certain recommendations found in the 2016 revised draft guidance, section VI.A., What to Include in an NDI Notification; Identity Information About the NDI and the Dietary Supplement, provide instruction and discuss information that is important in describing the identity of an NDI and the dietary supplement containing the NDI. We will recommend that certain information should be provided in table form for ease of reference and to help ensure completeness.

3. History of Use or Other Evidence of Safety

Certain recommendations in the 2016 revised draft guidance, sections VI.B., History of Use or Other Evidence of Safety, and VI.C., Summary of the Basis for Your Conclusion of Safety, as well as table 3, the Safety Testing Recommendations Matrix, provide instruction and discuss information that is important in describing the basis for which a dietary supplement containing the NDI will reasonably be expected to be safe. While the FD&C Act does not specify the type or amount of information that must be included in an NDIN, the notification should include a dietary supplement safety narrative containing the objective evaluation of the history of use or other evidence of safety cited in the notification, along with an explanation of how the evidence of safety provides a basis to conclude that the dietary supplement containing the NDI, when used under the conditions described in the NDIN, will reasonably be expected to be safe. Once finalized, the recommendations will instruct and help dietary supplement manufacturers and distributors understand what to consider when evaluating the safety of a dietary supplement containing an NDI and what should be included in an NDIN in this regard.

4. Electronic Submission

We developed an electronic portal that respondents may use to electronically submit their notifications to ODSP via COSM. COSM assists respondents filing regulatory submissions and is specifically designed to aid users wishing to file submissions with CFSAN. COSM allows safety and other information to be uploaded and submitted online via Form FDA 3880. This form provides a standard format to describe the history of use or other evidence of safety on which the manufacturer or distributor bases its conclusion that the NDI is reasonably expected to be safe under the conditions of use recommended or suggested in the labeling of the dietary supplement, as well as a description of the ingredient and other information. Firms that prefer to submit a paper notification in a format of their own choosing have the option to do so; however, Form FDA 3880 prompts a notifier to input the elements of an NDIN in a standard format that we will be able to review efficiently. Form FDA 3880 may be accessed at *https://www.fda.gov/food/new-dietary-ingredients-ndi-notification-process/how-submit-notifications-new-dietary-ingredient.*

In the **Federal Register** of August 2, 2023 (88 FR 50876), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment, which was not PRA-related, so we will not address it in this document.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; type of respondent; citation	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
NDIN submission; § 190.6	55	1	55	20	1,100
List Form and Template; Administrative Procedures; Section V	1	1	1	1	1
Written Authority; Master Files; Section IV.C.1 and 4	10	1	10	0.4 (24 minutes)	4
Table Form; Identity Specifications; Section VI.A	55	1	55	1	55
Manufacturing Process Information; Identity Information; Section VI.B. and C	55	1	55	5	275
Total					1,435

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

Our estimate is based on our experience with information collections related to past NDIN submissions. The estimated burden also reflects an industry average, although the burden associated with individual submissions may vary depending on the complexity of the notification. Due to a program change, we are revising this information collection request to include recommendations found in the 2016 revised draft guidance. Therefore, we have increased our total burden hour estimate by 335. However, the number of respondents remains the same.

We estimate that 55 respondents each submits 1 NDIN annually. We estimate that extracting and summarizing the relevant information from what exists in the company's files and presenting it in a format that meets the requirements of § 190.6 will take approximately 20 hours of work per notification. We believe that the burden of the premarket notification requirement is reasonable because we are requesting only safety and identity information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing the NDI is in compliance with the FD&C Act. If the required premarket notification is not submitted to FDA, section 413(a) of the FD&C Act provides that the dietary supplement containing the NDI is deemed to be adulterated under section 402(f) of the FD&C Act. Even if the notification is submitted as required, the dietary supplement containing the NDI is adulterated under section 402(f) of the FD&C Act unless there is a history of use or other evidence of safety establishing that the NDI, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. This requirement is separate from and additional to the requirement to submit a premarket notification for the NDI.

FDA's regulation on NDINs, § 190.6(a), requires the manufacturer or distributor of the NDI or dietary supplement containing the NDI to submit to FDA the information that forms the basis for its conclusion that the NDI, or dietary supplement containing the NDI, will reasonably be expected to be safe. Thus, § 190.6 only requires the manufacturer or distributor to extract and summarize information that should have already been developed to meet the safety

requirement in section 413(a)(2) of the FD&C Act.

We estimate that 95 percent of respondents submit electronically, leaving about 3 who submit their NDIN in paper format (5% × 55 = 2.75, rounded up to 3). However, we have seen a trend of decreased paper submissions over the past 2 years and expect usage to remain low. Thus, we estimate only one NDIN will be submitted in paper format. We estimate that information in this NDIN regarding the table of contents, names of contacts, and reference lists will be provided in list form. Because the underlying information should be already readily available, we estimate that it will take about 60 minutes to prepare the information in list form, which would create a burden of 1 hour (1 × 1 hour).

We estimate that 10 notifiers will each reference information once from a previous notification and will provide written authorization to do so. We estimate that it will take about 24 minutes to prepare a written authorization. We calculate that the burden for this activity will be 4 hours annually (10 notifiers × 1 authorization × 0.4 hour).

We estimate that 55 notifiers each will provide identity specifications in table form with their NDIN submissions. Because the underlining information should be already readily available, we estimate that it will take about 1 hour to prepare the information in table form, which would create a burden of 55 hours (55 tables × 1 hour).

We estimate that 55 notifiers each will provide information about the manufacturing process with their NDIN submissions. We estimate that it will take about 5 hours to prepare this information, which would create a burden of 275 hours (55 manufacturing process × 5 hours).

Dated: January 10, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–00732 Filed 1–16–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children; Correction

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

ACTION: Notice; correction.

SUMMARY: HRSA published a document in the **Federal Register** of January 9, 2024, concerning a meeting of the Advisory Committee on Heritable Disorders in Newborns and Children. The document contained incorrect HRSA contact information for further information and an incorrect date for requests to provide a written or oral statement. The notice originally stated that for further information, contact Kim Morrison at 301–822–4978. The correct contact information should be: Kim Morrison at 240–485–8419. The notice originally stated that requests for public comment were due on Tuesday, January 17, 2024. The correct date for requests for public comment is Thursday, January 18, 2024.

FOR FURTHER INFORMATION CONTACT: Kim Morrison, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland, 20857; 240–485–8419; or *ACHDNC@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of January 9, 2024, FR Doc. 2024–00264, page 1105, column 2, **FOR FURTHER INFORMATION CONTACT** section, paragraph 1, correct the ''Kim Morrison, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room, Rockville, Maryland 20857; 301–822–4978; or *ACHDNC@hrsa.gov*'' caption to read: ''Kim Morrison, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 240–485–8419; or *ACHDNC@hrsa.gov*.''

In the **Federal Register** of January 9, 2024, FR Doc. 2024–00264, page 1106, column 1, **SUPPLEMENTARY INFORMATION** section, paragraph 1, correct the ''Requests to provide a written statement or make oral comments to ACHDNC must be submitted via the registration website by 12 p.m. ET on Tuesday, January 17, 2024'' caption to read: ''Requests to provide a written statement or make oral comments to ACHDNC must be submitted via the registration website by 12 p.m. ET on Thursday, January 18, 2024.''

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–00739 Filed 1–16–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Rural Health Care Coordination Program Performance Improvement Measures, OMB No. 0906–0024—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than March 18, 2024.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Rural Health Care Coordination Program Performance Improvement Measures, OMB No. 0906–0024—Revision

Abstract: The Rural Health Care Coordination (Care Coordination) Program is authorized under 42 U.S.C. 254c(e) (Section 330A(e) of the Public Health Service Act) to promote rural health care services outreach by improving and expanding delivery of health care services through comprehensive care coordination strategies addressing a primary focus area: (1) heart disease, (2) cancer, (3) chronic lower respiratory disease, (4) stroke, or (5) maternal health. This authority permits the Federal Office of Rural Health Policy to award grants to