TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
R. Sterility		
14–582	Sterilization of health care products—Radiation—Part 4: Guidance on process control	ISO/TS 11137–4 First edition 2020–06.
14–583	Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices..	ANSI/AAMI ST98:2022.
S. Tissue Engineering		
No new entries at this time.		

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* Such standards are those that FDA has recognized by notice published in the **Federal Register** or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the **Federal Register**). FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to *CDRHStandardsStaff@fda.hhs.gov*. To be considered, such recommendations should contain, at a minimum, the information available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process.*

Dated: July 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2780]

Agency Information Collection Activities; Proposed Collection; 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 Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the procedure by which a manufacturer or distributor of a new dietary ingredient or of a dietary supplement containing a new dietary ingredient is to submit to FDA information upon which it has based its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe.

DATES: Either electronic or written comments on the collection of information must be submitted by October 2, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 2, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–2780 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification for a New

Dietary Ingredient.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical 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.

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) 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, recommends 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.*

Description of Respondents: The respondents to this collection of information are certain manufacturers and distributors in the dietary supplement industry.

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 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: July 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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