DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5280]

Dietary Supplements: New Dietary Ingredient Notification Procedures and Timeframes: Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Dietary Supplements: New Dietary Ingredient Notification Procedures and Timeframes: Guidance for Industry.'' The guidance focuses on frequently asked questions about the new dietary ingredient notification submission and review process. The guidance is intended to help manufacturers and distributors of new dietary ingredients and dietary supplements prepare and submit new dietary ingredient notifications to FDA.

DATES: The announcement of the guidance is published in the **Federal Register** on March 6, 2024

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

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–D–5280 for ''Dietary Supplements: New Dietary Ingredient Notification Procedures and Timeframes: Guidance for Industry.'' Received comments 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.'' We will review this copy, including the claimed confidential information, in our 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Dietary Supplement Programs, HFS–810, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Gerie Voss, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740; or Deirdre Jurand, Office of Regulations and Policy (HFS–024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Dietary Supplements: New Dietary Ingredient Notification Procedures and Timeframes: Guidance for Industry.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our current thinking on this topic. 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.

In the **Federal Register** of July 5, 2011 (76 FR 39111), we announced the availability of a draft guidance for industry entitled ''Draft Guidance for Industry; Dietary Supplements: New Dietary Ingredient Notifications and Related Issues'' and gave interested parties an opportunity to submit comments by October 3, 2011. Among other topics, the July 2011 draft guidance discussed FDA's views and recommendations on when an ingredient intended for use in a dietary supplement is a new dietary ingredient (NDI), when the requirement to submit a new dietary ingredient notification (NDIN) to FDA applies, the types of data and information that manufacturers and distributors should consider when they

evaluate the safety of a dietary supplement containing an NDI, what to include in an NDIN (including recommendations about identity and safety information), and the procedures for submitting an NDIN. We received significant comments and decided to issue a revised draft guidance.

In the **Federal Register** of August 12, 2016 (81 FR 53486), we announced the availability of a revised draft guidance for industry entitled ''Dietary Supplements: New Dietary Ingredient Notifications and Related Issues; Revised Draft Guidance for Industry'' to replace the July 2011 draft guidance. In the notice of availability, we gave interested parties an opportunity to submit comments on the 2016 revised draft guidance by October 11, 2016. On October 4, 2016, we extended the comment period for the revised draft guidance to December 12, 2016 (81 FR 68434). We received numerous comments on the 2016 revised draft guidance, including requests for FDA to separate the 2016 revised draft guidance into discrete sections for ease of use. The final guidance whose availability we are announcing through this document reflects that approach. The guidance finalizes Section V of the 2016 revised draft guidance, ''NDI Notification Procedures and Timeframes,'' as well as several related questions from other sections. Changes since the revised draft guidance include providing the following: additional clarity on the procedures for preparing and submitting an NDIN; technical updates related to recent changes to our online submission portal for NDINs; and more information about communications with FDA during the NDIN review process. In addition, we made editorial changes to improve clarity. We understand the importance of finalizing other parts of the 2016 revised draft guidance, and we plan to finalize other individual sections as we complete our review and analysis of those sections.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 190.6 and found in the guidance have been approved under OMB control number 0910–0330.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: February 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04718 Filed 3–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy

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

ACTION: Notice.

SUMMARY: HRSA is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

FOR FURTHER INFORMATION CONTACT: CDR George Reed Grimes, Director, Division of Injury Compensation Programs, Health Systems Bureau, HRSA, by mail at 5600 Fishers Lane, 8W25A, Rockville, Maryland 20857; or call (301) 443–9350.

SUPPLEMENTARY INFORMATION: Section 100.2 of the VICP's implementing regulation (42 CFR part 100) states that the revised amount of an average cost of a health insurance policy, as determined by the Secretary of Health and Human Services (the Secretary), is effective upon its delivery by the Secretary to the United States Court of Federal Claims (the Court) and will be published periodically in a notice in the **Federal Register**. This responsibility has been delegated to the Director, Division of Injury Compensation Programs. This figure is calculated using the most recent Medical Expenditure Panel Survey—Insurance Component data available as the baseline for the average monthly cost of a health insurance policy. This baseline is adjusted by the annual percentage increase/decrease obtained from the most recent annual Kaiser Family Foundation Employer Health Benefits Survey.

In 2023, the Medical Expenditure Panel Survey—Insurance Component, available at *www.meps.ahrq.gov,* published the annual 2022 average total single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was $7,590. This figure is divided by 12 to determine the cost per month of $632.50. The $632.50 figure is increased or decreased by the percentage change reported by the most recent Kaiser Family Foundation Employer Health Benefits Survey, available at *www.kff.org.* The increase from 2022 to 2023 was 7 percent. By adding this percentage increase, the calculated average monthly cost of a health insurance policy for a 12-month period is $676.78.

Therefore, the Secretary announces that the revised average cost of a health insurance policy under the VICP is $676.78 per month. In accordance with section 100.2, the revised amount was effective upon its delivery by the Secretary to the Court. Such notice was delivered to the Court on February 23, 2024.

Suma Nair,

Associate Administrator, Health System Bureau.

[FR Doc. 2024–04734 Filed 3–5–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or other reasonable accommodations, must notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*https://videocast.nih.gov/*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of