''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: Beverly Friedman or Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product EPKINLY (epcoritamab-bysp). EPKINLY is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Subsequent to this approval, the USPTO received patent term restoration applications for EPKINLY (U.S. Patent Nos. 10,465,006 and 10,544,220) from Genmab A/S, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated January 30, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of EPKINLY represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for EPKINLY is 1,909 days. Of this time, 1,668 days occurred during the testing phase of the regulatory review period, while 241 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* February 27, 2018. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 27, 2018.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* September 21, 2022. FDA has verified the applicant's claim that the biologics license application (BLA) for EPKINLY (BLA B761324) was initially submitted on September 21, 2022.

3. *The date the application was approved:* May 19, 2023. FDA has verified the applicant's claim that BLA B761324 was approved on May 19, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 675 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: May 7, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08450 Filed 5–13–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1134]

Infant Formula Nutrient Requirements; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting information and data to begin the nutrient review process for infant formula. We are taking this action, in part, to continue to ensure the nutritional adequacy of infant formula sold in the United States. We intend to use the information and data to help determine what type(s) of actions, if any, should be taken.

DATES: Either electronic or written comments on the notice must be submitted by September 11, 2025.

ADDRESSES: You may submit comments and information 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 September 11, 2025. 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–2025–N–1134 for ''Infant Formula Nutrient Requirements; Request for Information.'' 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.'' 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.

FOR FURTHER INFORMATION CONTACT: Carrie Assar, Office of Critical Foods, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1453, or Holli Kubicki, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

Section 412(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350a(i)) establishes requirements for the nutrient content of infant formulas. Under section 412(i)(2) of the FD&C Act, the Secretary of Health and Human Services is authorized to revise the list of required nutrients and the required level for any required nutrient. In addition, section 412(i)(1) of the FD&C Act requires the Secretary to review the table of required nutrients ''every 4 years as appropriate,'' taking into consideration ''any new scientific data or information related to infant formula nutrients, including international infant formula standards.'' These authorities have been delegated to the Commissioner of Food and Drugs. The table in section 412(i) of the FD&C Act and FDA regulations at 21 CFR 107.100 specify that infant formulas must contain 30 nutrients; minimum levels for each nutrient and maximum levels for 10 of the nutrients are also specified.

Although FDA regularly reviews individual nutrient requirements for infant formula, our last comprehensive review was in 1998 (Ref. 1). We last updated the table in 21 CFR 107.100 in 2015 to add the mineral selenium to the list of required nutrients and to establish minimum and maximum levels of selenium in infant formula (80 FR 35834 (June 23, 2015)).

On March 18, 2025, the Department of Health and Human Services and FDA announced ''Operation Stork Speed'' to expand options for safe, reliable, and nutritious infant formula for American families. As part of Operation Stork Speed, FDA announced a set of actions and initiatives focused on infant formula, such as beginning the nutrient review process and increasing testing for heavy metals and other contaminants. We are also encouraging companies to develop new infant formulas and clarify opportunities to help inform consumers about formula ingredients. These enhanced FDA commitments are focused on making sure a strong supply of infant formula—which is often the sole source of nutrition for infants—remains available for one of our nation's most vulnerable populations.

II. Issues for Consideration and Request for Information

FDA is issuing this request for information to begin the nutrient review process for infant formula intended for healthy, full-term infants. Specifically, FDA is interested in information that would help us determine whether there is a need to revise the existing nutrient requirements in 21 CFR 107.100, taking into consideration any new scientific data or information related to infant formula nutrients, including international infant formula standards. For purposes of this request for information, the term ''nutrient'' means

any vitamin, mineral, or other substance or ingredient that is required in accordance with the table set out in section 412(i)(1) of the FD&C Act or by 21 CFR 107.100, or that is identified as essential for infants by the Food and Nutrition Board of the Institute of Medicine through its development of a Dietary Reference Intake, or that has been identified as essential for infants by FDA through a **Federal Register** publication (see 21 CFR 106.3 (definition of ''nutrient'')). We invite comment on the questions below. Please explain your answers and provide references and data, if possible.

1. What new scientific data or information since the 1998 comprehensive assessment (Ref. 1) should we consider regarding nutrient requirements for healthy, full-term infants that are associated with positive short- and/or long-term health outcomes?

2. What scientific data or information have emerged since the 1998 comprehensive assessment (Ref. 1) regarding nutrient intakes for healthy, full-term infants that are associated with poor short- and/or long-term health outcomes?

3. Which existing nutrients required in 21 CFR 107.100 should we review? Please explain your rationale.

4. For the nutrients required in 21 CFR 107.100, what, if any, adjustments should be made to existing minimum or maximum levels? For the 20 nutrients with only a minimum level, which, if any, should have a maximum level added? Please explain your rationale. For example, describe how changes might positively impact health outcomes.

5. What other nutrients (*e.g.,* docosahexaenoic acid and arachidonic acid) or specifications for nutrients (*e.g.,* ratio of linoleic acid to alpha-linolenic acid), if any, should we consider adding to 21 CFR 107.100? Please explain your rationale.

6. Which nutrients, if any, should we remove from 21 CFR 107.100? Please explain your rationale.

III. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Raiten, D.J., J.M. Talbot, and J.H. Waters, Life Sciences Research Office, American Society for Nutritional Sciences, ''Assessment of Nutrient Requirements for Infant Formulas,'' *Journal of Nutrition,* 128 (11 Suppl) (November 1998): i–iv, 2059S–2293S. Available at *https://doi.org/10.1093/jn/128.suppl_11.2059S.*

Dated: May 7, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–08419 Filed 5–13–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0479]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before June 13, 2025.

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 information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Jamie Kim, The Office of Population Affairs (OPA), Office of the Assistant Secretary for Health at *Jamie.Kim@hhs.gov* or (240) 453–2817. When submitting comments or requesting information, please include the document identifier 0990–30D and the project title for reference: Family Planning Annual Report (FPAR).

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

The Office of Population Affairs (OPA), within the Office of the Assistant Secretary for Health, seeks approval for a reinstatement with changes for their encounter level data collection for the Family Planning Annual Report (FPAR). This was previously approved by OMB under OMB No. 0990–0479, (expiration February 28, 2025). Annual submission of the FPAR is required of all Title X Family Planning Services grantees for purposes of monitoring and reporting program performance.

Need and Proposed Use of the Information

OPA's Title X Family Planning Program is the only federal grant program dedicated solely to providing comprehensive family planning and related preventive health services. The FPAR is the only source of annual, uniform reporting by all Title X services grantees funded under Section 300 of the Public Health Service Act. The FPAR 2.0 system provides consistent, national-level data on the Title X Family Planning program and its users. OPA assembles and analyzes comparable and relevant program data to answer questions about the characteristics of the population served, the provision and use of services, and the impact of the program on certain family planning outcomes. FPAR 2.0 collects a standard set of data elements pertaining to users and encounters, such as user demographics, service delivery, and family planning intentions and methods. Encounter level data collected through FPAR 2.0 improves the quality of data reported to OPA and reduces reporting burden by grantees. Additionally, the more granular data collected with FPAR 2.0 contributes to a learning healthcare environment by greatly expanding the options for data analysis and reporting—for example, through interactive data dashboards and visualizations, customized tabulations and reports, and application of analytics and statistical analyses on the encounter-level data files.

Information from FPAR 2.0 is important to OPA for many reasons, and is used to:

(1) Monitor compliance with statutory requirements, regulations, and operational guidance.

(2) Comply with accountability and federal performance requirements for Title X family planning funds.

(3) Guide strategic and financial planning, to monitor performance, to respond to inquiries from policymakers