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 drug 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 drug product, YORVIPATH (palopegteriparatide) indicated for the treatment of hypoparathyroidism in adults. Subsequent to this approval, the USPTO received patent term restoration applications for YORVIPATH (U.S. Patent Nos. 11,857,603; 11,890,326; and 11,918,628) from Ascendis Pharma Bone Diseases A/S and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated March 17, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of YORVIPATH 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 YORVIPATH is 1,978 days. Of this time, 1,268 days occurred during the testing phase of the regulatory review period, while 710 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* March 13, 2019. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 13, 2019.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* August 31, 2022. FDA has verified the applicant's claim that the new drug application (NDA) for YORVIPATH (NDA 216490) was initially submitted on August 31, 2022.

3. *The date the application was approved:* August 9, 2024. FDA has verified the applicant's claim that NDA 216490 was approved on August 9, 2024.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 158 days, 186 days, or 221 days of patent term extensions.

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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16269 Filed 8–25–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–E–1548; FDA–2023–E–1550]

Determination of Regulatory Review Period for Purposes of Patent Extension; CAMZYOS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or the Agency) published a notice in the **Federal Register** of February 29, 2024. After review of the calculation of the applicable regulatory review period of the biologic product CAMZYOS (U.S. patent numbers 9,181,200; 9,585,883) in that notice, FDA has determined that a revision of the **SUPPLEMENTARY INFORMATION** section is warranted. This notice corrects the applicable regulatory review period language.

FOR FURTHER INFORMATION CONTACT: 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:

Correction

In the **Federal Register** of February 29, 2024 (89 FR 14880), on page 14881, second column, under II. Determination of Regulatory Review Period, the first two sentences of the section should be corrected to read as follows:

FDA has determined that the applicable regulatory review period for CAMZYOS is 2,722 days. Of this time, 2,266 days occurred during the testing phase of the regulatory review period, while 456 days occurred during the approval phase.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16273 Filed 8–25–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0123]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Generally Recognized as Safe (GRAS): Notifications and Convening Panels

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 September 25, 2025.

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 0910–0342. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Substances Generally Recognized as Safe (GRAS): Notifications and Convening Panels—21 CFR 170, Subpart E and 21 CFR 570, Subpart E

OMB Control Number 0910–0342—Revision

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that all food additives (as defined by section 201(s) (21 U.S.C. 321(s)) be approved by FDA before they are marketed. Section 409 of the FD&C Act (21 U.S.C. 348) establishes a premarket approval requirement for ''food additives.'' Section 201(s) of the FD&C Act provides an exclusion to the definition of food additive, and thus from the premarket approval requirement, for uses of substances that are GRAS by qualified experts. The GRAS provision of section 201(s) of the FD&C Act is implemented in 21 CFR part 170 (part 170) and 21 CFR part 570 (part 570) for human food and animal food, respectively. Part 170, subpart E, and part 570, subpart E, establish a standard format for the submission of a notice. Information submitted to FDA in a GRAS notice by respondents is necessary to allow us to administer efficiently the various FD&C Act provisions that apply to the use of substances added to food, specifically with regard to whether a substance is GRAS under the conditions of its intended use or is a food additive subject to premarket review. We use the information collected through the GRAS notification procedures to complete our evaluation within specific timelines.

Form FDA 3667, entitled ''Generally Recognized as Safe Notice'' (*https://www.fda.gov/media/85886/download*), provides a standardized format for the submission of information and is intended to assist respondents with the submission of GRAS notices. Form FDA 3667 and any attachments may be submitted in electronic format via the Centralized Online Submission Module (*https://www.fda.gov/food/registration-food-facilities-and-other-submissions/centralized-online-submission-module-cosm*), or may be submitted in paper format, or as electronic files on physical media with paper signature page. For submissions to the Center for Veterinary Medicine, respondents may continue to send GRAS notices in paper format, or as electronic files on physical media with paper signature page to the Agency.

For efficiency of Agency operations, we are revising the information collection to account for burden that may be attributable to the guidance document entitled ''Best Practices for Convening a Generally Recognized as Safe Panel'' (December 2022) (*https://www.fda.gov/media/109006/download*), currently approved in OMB control number 0910–0911. The guidance document was developed to assist persons who choose to convene a panel of experts in support of a conclusion that the use of a substance in food is GRAS. Specifically, the guidance document includes recordkeeping recommendations and disclosure recommendations pertaining to the administration of GRAS panel and GRAS panel membership.

Description of Respondents: The respondents to this collection of information are manufacturers of substances used in human food and animal food and feed. Respondents also include persons (''proponents'') who are responsible for a conclusion that a substance may be used in food on the basis of the GRAS provision of the FD&C Act when such persons convene a GRAS panel to evaluate whether the available scientific data, information, and methods establish that the substance is safe under the conditions of its intended use in human food or animal food. Respondents also include members and prospective members of GRAS panels. The term ''GRAS panel'' is defined as a panel of individuals convened for the purpose of evaluating whether the available scientific data, information, and methods establish that a substance is safe under the conditions of its intended use in food.

In the **Federal Register** of June 27, 2025 (90 FR 27642), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
GRAS notification procedure for human food; 170.210–170.280 (part 170, subpart E)	100	1	100	170	17,000
GRAS notification procedure for animal food and animal feed; 570.210–570.280 (part 570, subpart E)	12	1	12	170	2,040
Total			125		19,040

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

In row 2 of table 1, we are decreasing our estimate for the number of respondents submitting GRAS notices for animal food and animal feed from 25 to 12, which results in a decrease of 2,210 burden hours (4,250 hours minus 2,040 hours). This estimate is based on the number of submissions we received over the last 3 years.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; guidance document section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintaining written GRAS panel policy; V. Recommendations	696	1	696	2	1,392
Application of written GRAS panel policy to GRAS panel members; V. Recommendations	94	6	564	16	9,024
Total	.....	.....	1,260	.....	10,416

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

Row 1 of table 2 reflects a decrease in our estimate of the average burden per recordkeeping from 40 hours to 2 hours annually. We believe that respondents will have realized burden associated with the initial documentation of written GRAS panel policies and have modified our estimate to reflect burden associated with maintaining the applicable records.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; guidance document section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Potential GRAS panel members provide information to the proponents of GRAS conclusions; V. Recommendations	564	1	564	4	2,256

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

We have made no change in our estimate associated with the disclosure recommendations discussed in the guidance document.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16268 Filed 8–25–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–5278; FDA–2024–E–5279; FDA–2024–E–5280; FDA–2024–E–5281]

Determination of Regulatory Review Period for Purposes of Patent Extension; NEMLUVIO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for NEMLUVIO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by October 27, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by February 23, 2026. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 27, 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.''