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