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, YCANTH (cantharidin). YCANTH is indicated for topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older. Subsequent to this approval, the USPTO received a patent term restoration application for YCANTH (U.S. Patent No. 11,052,064) from Verrica Pharmaceuticals, and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated February 7, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of YCANTH 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 YCANTH is 2,285 days. Of this time, 877 days occurred during the testing phase of the regulatory review period, while 1,408 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:* April 20, 2017. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 20, 2017.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* September 13, 2019. FDA has verified the applicant's claim that the new drug application (NDA) for YCANTH (NDA 212905) was initially submitted on September 13, 2019.

3. *The date the application was approved:* July 21, 2023. FDA has verified the applicant's claim that NDA 212905 was approved on July 21, 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 application for patent extension, this applicant seeks 745 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: August 30, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20052 Filed 9–5–24; 8:45 am]

BILLING CODE 4164–01–P

Dated: September 3, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20115 Filed 9–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–N–1464 and FDA–2023–N–2781]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
New Animal Drugs for Investigational Use	0910–0117	8/31/2027
Data To Support Drug Product Communications	0910–0695	8/31/2027