

include other regulatory authorities and industry associations from around the world (refer to <https://www.ich.org>).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

On February 7, 2024, the ICH Assembly endorsed the draft guideline entitled "E2D(R1) Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports" and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Efficacy Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Efficacy Expert Working Group.

The draft guidance aims to improve the quality of postapproval safety information by revising the 2003 guidance entitled "E2D Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting," which introduced an internationally standardized procedure for gathering and reporting postapproval safety data. Building on the standardized recommendations from the 2003 guidance, this draft guidance aims to clarify the use of new or more frequently applied postapproval safety sources and update terminology and standards for postmarket adverse event reporting.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on "E2D(R1) Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports." 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.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information pertaining to postmarketing adverse drug experience reporting have been approved under OMB control number 0910–0230. The collection of information for FDA adverse event reporting and electronic submissions using the Electronic Submission Gateway and the Safety Reporting Portal has been approved under OMB control number 0910–0291. The collections of information pertaining to the issuance of "Dear Health Care Provider Letters: Improving Communication of Important Safety Information" have been approved under OMB control number 0910–0754.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.regulations.gov>, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/vaccines-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

Dated: March 8, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–05381 Filed 3–13–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–E–1551]

### Determination of Regulatory Review Period for Purposes of Patent Extension; VTAMA

**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 VTAMA and is publishing this notice of that determination as required by law. FDA has made the

determination because of the submission of an application 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 drug product.

**DATES:** Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by May 13, 2024. 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 September 10, 2024. 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 May 13, 2024. 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-2023-E-1551 for “Determination of Regulatory Review Period for Purposes of Patent Extension; VTAMA.” 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.” The Agency will review this copy, including the claimed confidential information, in its 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 § 10.20 (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:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, 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 biological 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 drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 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, VTAMA (tapinarof) is indicated for the topical treatment of plaque psoriasis in adults. Subsequent to this approval, the USPTO received a patent term restoration application for VTAMA (U.S. Patent No. 10,195,160) from Dermavant Sciences, GmbH and the USPTO requested FDA’s

assistance in determining the patent’s eligibility for patent term restoration. In a letter dated September 28, 2023, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of VTAMA 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 VTAMA is 3,134 days. Of this time, 2,771 days occurred during the testing phase of the regulatory review period, while 363 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:* October 25, 2013. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on October 25, 2013.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* May 26, 2021. FDA has verified the applicant’s claim that the new drug application (NDA) for VTAMA (NDA 215272) was initially submitted on May 26, 2021.

3. *The date the application was approved:* May 23, 2022. FDA has verified the applicant’s claim that NDA 215272 was approved on May 23, 2022.

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 4 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: March 11, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–05408 Filed 3–13–24; 8:45 am]

BILLING CODE 4164–01–P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS–0990–new]

**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, Improving Customer Experience (OMB Circular A–11, Section 280 Implementation).

**DATES:** Comments on the ICR must be received on or before April 15, 2024.

**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](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov)

or (202) 264–0041, or [PRA@HHS.GOV](mailto:PRA@HHS.GOV). When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

**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.

OMB Circular A–11 Section 280 established government-wide standards for mature customer experience organizations in government and measurement. To enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.*, in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. HHS will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. It will also provide government-wide data on customer experience that can be displayed on [performance.gov](http://performance.gov) to help build

transparency and accountability of Federal programs to the customers they serve.

*Title of the Collection:* Improving Customer Experience (OMB Circular A–11, Section 280).

*Type of Collection:* Father Generic ICR.

OMB No. 0990–NEW Office of the Secretary, Assistant Secretary Administration.

*Abstract:* The Department of Health and Human Services, Office of the Secretary, Assistant Secretary Administration is requesting approval by OMB on a new Father Generic Information Collection Request. OMB Circular A–11 Section 280 established government-wide standards for mature customer experience organizations in government and measurement. To enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.*, in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. HHS will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. It will also provide government-wide data on customer experience that can be displayed on [performance.gov](http://performance.gov) to help build transparency and accountability of Federal programs to the customers they serve (Implementation).

**ESTIMATED ANNUALIZED BURDEN TABLE**

Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden hours per response	Total burden hours
Participants in customer interviews .....	500	1	1	500
Participants in focus groups .....	450	1	90/60	675
Participants of feedback surveys .....	2,000,000	1	3/60	100,000