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 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 JIVI (antihemophilic factor (recombinant), PEGylated-aucl). JIVI is indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for: (1) on-demand treatment and control of bleeding episodes; (2) perioperative management of bleeding; and (3) routine prophylaxis to reduce the frequency of bleeding episodes. Subsequent to this approval, the USPTO received a patent term restoration application for JIVI (U.S. Patent No. 7,632,921) from Bayer HealthCare LLC, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 12, 2019, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of JIVI 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 JIVI is 2,991 days. Of this time, 2,626 days occurred during the testing phase of the regulatory review period, while 365 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:* June 23, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 23, 2010.

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):* August 30, 2017. FDA has verified the applicant's claim that the biologics license application (BLA) for JIVI (BLA 125661) was initially submitted on August 30, 2017.

3. *The date the application was approved:* August 29, 2018. FDA has verified the applicant's claim that BLA 125661 was approved on August 29, 2018.

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 1,677 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 section 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 section 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with section 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 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05570 Filed 3–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–2856]

Pharmacogenomic Data Submissions; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Pharmacogenomic Data Submissions.'' This draft guidance is intended to facilitate progress in the field of pharmacogenomics and the use of pharmacogenomic data in drug development. The draft guidance is intended to clarify the contexts in which pharmacogenomic study findings and data must be included in submissions related to investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) based on the FDA's regulations. In addition, this document provides recommendations to sponsors and applicants on the format and content of the pharmacogenomic data submissions.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 20, 2023.

ADDRESSES: You may submit comments as follows:

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–2022–D–2856 for ''Pharmacogenomic Data Submissions.'' Received comments 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 office 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or the Center for Biologics Evaluation and Research, Office of Communication, Outreach, and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20903. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

For Center of Drug Evaluation and Research: Michael Pacanowski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2132, Silver Spring, MD 20993, 301–796–3919.

For Center of Biologics Evaluation and Research: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pharmacogenomic Data Submissions.'' The draft guidance outlines FDA's expectations for the submission of data from pharmacogenomic studies considering the advances in genomics research that have occurred since FDA published final guidance on ''Pharmacogenomic Data Submissions'' in 2005. This guidance, when finalized, will replace the 2005 final guidance.

Pharmacogenomic studies that evaluate the effect of variations in DNA or RNA characteristics on drug concentrations or response have the potential to help identify sources of inter-individual variability and characterize the pharmacologic effects of a drug. In some cases, pharmacogenomic studies can identify biomarkers that make it possible to individualize therapy. In addition, pharmacogenomic biomarkers that have well-accepted mechanistic and clinical significance are currently being integrated into drug development (*e.g.,* enriched clinical trial designs) and clinical practice (*e.g.,* clinical testing to determine dose).

Sponsors submitting or holding INDs, NDAs, or BLAs are subject to FDA requirements for submitting data to the Agency that are relevant to drug safety and effectiveness (including 21 CFR 312, 314, and 601). However, the regulations were developed before the advent of widespread animal or human genetic testing (*e.g.,* high-throughput DNA sequencing) or gene expression testing and do not specifically address when such data must be submitted. This document, when final, will constitute FDA's current thinking about pharmacogenomic study results and the associated data required to be submitted in an IND, NDA, or BLA, as well as the FDA's recommendations as to the level of detail and format for reporting.

In addition, this draft guidance has also removed references to the Voluntary Genomic Data Submission program (VGDS; later referred to as Voluntary eXploratory Data Submission program, or VXDS). The VGDS program created a pathway for voluntary exchanges between FDA and the pharmaceutical industry or other stakeholders regarding genomic and other biomarker studies in the context of individual drug development programs. The program helped the Agency gain knowledge regarding genomics research in the context of drug development and

practical experience with data submission and analysis. Since it was first introduced in 2003, the VXDS program has received over 50 voluntary submissions. In recent years, FDA has established additional pathways to interact with stakeholders on biomarker development, such as the Biomarker Qualification Program and Critical Path Innovation Meetings. Given the availability of these programs and decreasing use of the program, FDA is considering ending the program, and references to the VGDS program have been removed from this draft guidance. However, FDA seeks public feedback on the following specific issues:

- The VGDS program created a pathway and infrastructure for stakeholders to voluntarily submit genomic or other data to FDA, when such data are not otherwise required to be submitted to FDA. Such a submission pathway could support regulatory science initiatives (*e.g.,* aggregating data from multiple programs to support endpoint development). While it is FDA's plan to discontinue the VGDS program in its current form, FDA requests feedback on the utility of maintaining a voluntary submission pathway that is of value to both FDA and the pharmaceutical industry.
- FDA requests public input on particular platforms or technologies that would benefit most from standardization.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on pharmacogenomic data submissions to the Agency. 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 50 and 56 pertaining to informed consent have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 312 pertaining to submissions of investigational new drug applications (IND), including clinical trial design and study protocols, IND Safety Reports, Annual Reports and voluntary pharmacogenomic data have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to submissions of new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to submissions of biologics license applications have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.regulations.gov*, or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics*.

Dated: March 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05561 Filed 3–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–E–2805]

Determination of Regulatory Review Period for Purposes of Patent Extension; IC–8 APTHERA INTRAOCULAR LENS

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 IC–8 APTHERA INTRAOCULAR LENS 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 medical device.

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 19, 2023. 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 18, 2023. 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 19, 2023. 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:

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- 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