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of the program, FDA is considering ending the program, and references to the VGDS program have been removed from this draft guidance.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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on pharmacogenomic data submissions to the Agency.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:

- *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–E–2805 for Determination of Regulatory Review Period for Purposes of Patent Extension; IC–8 APTHERA INTRAOCULAR LENS. 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 section 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 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device IC–8 APTHERA INTRAOCULAR LENS. IC–8 APTHERA INTRAOCULAR LENS is indicated for unilateral implantation for the visual correction of aphakia and to create monovision in patients age 22 or older who have been diagnosed with bilateral operable cataract, who have up to 1.5D of astigmatism in the implanted eye and who do not have a history of retinal disease and who are not predisposed to experiencing retinal disease in the future. Subsequent to this approval, the USPTO received a patent term restoration application for IC–8 APTHERA INTRAOCULAR LENS (U.S. Patent No. 9,005,281) from AcuFocus, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 10, 2023, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of IC–8 APTHERA INTRAOCULAR LENS 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 IC–8 APTHERA INTRAOCULAR LENS is 1,341 days. Of this time, 827 days occurred during the testing phase of the regulatory review period, while 514 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) became effective:* November 21, 2018. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) for human tests to begin, as required under section 520(g) of the FD&C Act, became effective November 21, 2018.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* February 24, 2021. FDA has verified the applicant's claim that the premarket approval application (PMA) for IC–8 APTHERA INTRAOCULAR LENS (PMA 210005) was initially submitted February 24, 2021.

3. *The date the application was approved:* July 22, 2022. FDA has verified the applicant's claim that PMA 210005 was approved on July 22, 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 928 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 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05641 Filed 3–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Security Assistant Deputy Secretary of National Security Statement of Delegation of Authority

Notice is hereby given that I have delegated to the Assistant Deputy Secretary for National Security within the Office of the Secretary (OS), Immediate Office of the Secretary (IOS), Office of National Security (ONS), the authorities vested in me as the Secretary of Health and Human Services for managing the Controlled Unclassified Information Program under Executive Order 13556, now and hereafter.

This authority may be redelegated, but only within ONS. Exercise of this authority shall be in accordance with established policies, procedures, guidelines, and regulations as prescribed by the E.O. 13556 and 32 CFR part 2002 ''Controlled Unclassified Information.''

This delegation of authority is effective immediately upon signature.

Dated: March 15, 2023.

Xavier Becerra,

Secretary.

[FR Doc. 2023–05637 Filed 3–17–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

COVID–19 Emergency Use Authorization Declaration

ACTION: Notice of amendment.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On March 15, 2023, the Secretary amended the February 4, 2020 determination made pursuant to section 564 of the FD&C Act and determined pursuant to his authority under section 564(b)(1)(C) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad and that involves a biological agent, namely the novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV, or SARS–CoV–2).

DATES: The section 564(b)(1)(C) determination that was originally issued on February 4, 2020, is amended as of March 15, 2023.

FOR FURTHER INFORMATION CONTACT: Paige Ezernack: 202–260–0365, *paige.ezernack@hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an EUA authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, an unlicensed biological product, or an unapproved animal drug; or (2) an unapproved use of an approved drug, approved or cleared device, licensed biological product, or conditionally approved animal drug. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a chemical, biological, radiological, or nuclear (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a CBRN agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may then issue a declaration(s) that circumstances exist that justify the issuance of an EUA(s), at which point the FDA Commissioner may issue an EUA(s) for certain products if the criteria for issuance under section 564 of the FD&C Act are met. The section 564 declaration(s) terminate only when the Secretary of HHS determines that the termination requirements of section 564(b)(2)(A) of the FD&C Act are met. Additionally, section 564(b)(3) provides that the Secretary shall provide advance notice, by publication in the **Federal Register**, that a declaration(s) under section 564 will be terminated.

II. Determination by the Secretary of Health and Human Services

On February 4, 2020, pursuant to his authority under section 564 of the FD&C Act, the Secretary of HHS determined that the circumstances in section 564(b)(1) exist because ''there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV).'' 85 FR 7316.

It is now well established that SARS–CoV–2 is constantly evolving and continues to be an ongoing challenge. As of January 30, 2023, SARS–CoV–2 has led to over 753 million cases of COVID–19, including 6.8 million deaths worldwide. This is due, in part, to variations in the virus that may allow it to spread more easily or make it resistant to treatments or decreased vaccine effectiveness. There is also a risk that eventually a variant will emerge that will escape the protection provided by the current generation of vaccines against severe disease. For example, the SARS–CoV–2 Omicron variant has continued to evolve into sublineages with additional mutations in the spike glycoprotein and the