FDA provided recommendations on master protocols for COVID–19 drug and biological products in the guidance entitled ''COVID–19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention,'' which posted May 2021 and was announced in the **Federal Register** on June 24, 2021 (86 FR 33309) (hereafter ''2021 COVID–19 Master Protocols Guidance''). FDA issued the guidance to communicate its policy for the duration of the COVID–19 public health emergency (PHE) declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). Furthermore, in the **Federal Register** of March 13, 2023 (88 FR 15417), FDA listed the guidance documents that will no longer be effective with the expiration of the PHE declaration, guidances that FDA was revising to continue in effect for 180 days after the expiration of the PHE declaration to provide a period for stakeholder transition and then would no longer be in effect, and guidances that FDA was revising to continue in effect for 180 days after the expiration of the PHE declaration during which time FDA planned to further revise the guidances. The 2021 COVID–19 Master Protocols Guidance is included in the latter category. The 2021 COVID–19 Master Protocols Guidance was revised to remain in effect for 180 days post expiration of the PHE declaration, and then revised again to remain in effect until March 7, 2024, so that FDA could further revise the 2021 guidance.

FDA is issuing this draft guidance because many of the issues addressed in the 2021 guidance arise outside the context of the COVID–19 PHE. The recommendations in this draft guidance apply to a range of therapeutic areas, not just COVID–19. The draft guidance also provides a more comprehensive discussion of many of the design and analysis topics covered in the 2021 COVID–19 Master Protocols Guidance. For example, the draft guidance provides more detailed considerations related to randomization, the choice of control group, informed consent, blinding to treatment assignment, adaptive design, multiplicity, comparisons between drugs, and the evaluation of drug safety. The draft guidance also expands on considerations for trial oversight, data sharing, dissemination of information, and submissions to support regulatory review. The draft guidance, when finalized, will represent the Agency's current thinking on the use of master protocols in drug and biological product development.

FDA is issuing this guidance to satisfy, in part, a mandate under section 3607(b)(2)(C–F) of the Food and Drug Omnibus Reform Act of 2022 (FDORA). Consistent with the FDORA mandate, this guidance discusses recommendations for clinical trials to streamline logistics and facilitate the efficient collection and analysis of data, as well as important principles for the evaluation of effectiveness, recommendations for communication between sponsors and FDA, and considerations related to ensuring participant safety and data integrity in such trials.

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 ''Master Protocols for Drug and Biological Product Development.'' 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.

FDA is also announcing that the 2021 COVID–19 Master Protocols Guidance will be withdrawn upon publication of this draft guidance. FDA has determined that the 2021 COVID–19 Master Protocols Guidance is no longer needed because this new draft is available and its recommendations, when finalized, will be applicable outside the context of the COVID–19 PHE.

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 in 21 CFR part 312 for the submission of investigational new drug applications (INDs), including protocols, protocol amendments, and information amendments, have been approved under OMB control number 0910–0014. The information collections for new drug application (NDA) regulations (including abbreviated new drug applications (ANDAs)) (21 CFR part 314) and related guidances are approved under OMB control number 0910–0001, and our biological licensing applications (BLA) regulations (21 CFR part 601) are approved under OMB control number 0910–0338. The collections of information in 21 CFR parts 50 and 56 for the protection of human subjects and institutional review boards have been approved under OMB control number 0910–0130. The collections of information related to the protection of human subjects under 45 CFR part 46 and to IRB recordkeeping under 45 CFR 46.115 have been approved under OMB control number 0990–0260. The collections of information in 21 CFR part 11, Electronic Records; Electronic Signatures, have been approved under OMB control number 0910–0303. The information collection requirements in FDA's guidance for industry entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control number 0910–0581. The information collection requirements in FDA's guidance for industry entitled ''Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring'' and FDA's final guidance for industry entitled ''A Risk-Based Approach to Monitoring of Clinical Investigations'' have been approved under OMB control number 0910–0733. The information collections in FDA's guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' have been approved under OMB control number 0910–0765.

III. Electronic Access

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

Dated: December 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28210 Filed 12–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–3017]

Determination of Regulatory Review Period for Purposes of Patent Extension; Emgality

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 Emgality 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 biological 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 February 20, 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 June 20, 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 February 20, 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–2019–E–3017 ''For Determination of Regulatory Review Period for Purposes of Patent Extension; EMGALITY.'' 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 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 Emgality (galcanezumab-gnlm). Emgality is

indicated for the preventive treatment of migraine in adults. Subsequent to this approval, the USPTO received a patent term restoration application for Emgality (U.S. Patent No. 9,505,838) from Eli Lilly and Company, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 24, 2020, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of Emgality 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 Emgality is 2,738 days. Of this time, 2,372 days occurred during the testing phase of the regulatory review period, while 366 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:* April 1, 2011. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 1, 2011.

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):* September 27, 2017. FDA has verified the applicant's claim that the biologics license application (BLA) for Emgality (BLA B761063) was initially submitted on September 27, 2017.

3. *The date the application was approved:* September 27, 2018. FDA has verified the applicant's claim that BLA B761063 was approved on September 27, 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 403 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: December 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28233 Filed 12–21–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–3287]

Determination of Regulatory Review Period for Purposes of Patent Extension; Copiktra

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 Copiktra 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 February 20, 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 June 20, 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 February 20, 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–2019–E–3287 for ''Determination of