modified by the Phase I revisions. In addition, the FEIS also complies with the GSA Public Buildings Service NEPA Desk Guide and other relevant federal and state laws and regulations and executive orders and integrates the consultation processes required under Section 106 of the National Historic Preservation Act and Section 7 of the Endangered Species Act with the NEPA process.

Anamarie Crawley,

Director, R10 Facilities Management Division Northwest/Arctic Region 10 U.S. General Services Administration.

[FR Doc. 2024–19122 Filed 9–5–24; 8:45 am]

BILLING CODE 6820–DL–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Community Preventive Services Task Force (CPSTF)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention, within the Department of Health and Human Services, announces the next meeting of the Community Preventive Services Task Force (CPSTF) on October 16–17, 2024.

DATES: The meeting will be held on Wednesday, October 16, 2024, from 9 a.m. to 5 p.m. EDT, and Thursday, October 17, 2024, from 9 a.m. to 5 p.m. EDT.

ADDRESSES: The meeting will be available to the public via web conference.

FOR FURTHER INFORMATION CONTACT: Kenya Turner, Office of Science, Office of Scientific Evidence and Recommendations, Community Guide Program; Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–H21–10, Atlanta, GA 30329. Telephone: (404) 718–4592; Email: *CPSTF@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Meeting Accessibility: The CPSTF meeting will be shown via web conference.

All meeting attendees must register by October 9, 2024. CDC will email web conference login information and the agenda to registrants from the *CPSTF@cdc.gov* mailbox approximately two weeks before the meeting start date.

To register for the meeting, individuals should send an email to *CPSTF@cdc.gov* and include the following information: name, title, organization name, organization address, phone, and email.

Public Comment: Individuals who would like to make public comments during the October meeting must state their desire to do so in an email to the *CPSTF@cdc.gov* mailbox no later than October 9, 2024. The request should include name, organizational affiliation, and topic to be addressed. Public comment must be relevant to one of the topics proposed for the meeting. The requestor will receive instructions related to the public comment process for this meeting after the request is received. A public comment period follows the CPSTF's discussion of each systematic review and will be limited to no more than three minutes per person. Public comments may be used to inform task force discussions and will be included in the meeting summary.

Background on the CPSTF: The CPSTF is an independent, nonfederal panel whose members are appointed by the CDC Director. CPSTF members represent a broad range of research, practice, and policy expertise in prevention, wellness, health promotion, and public health. The CPSTF was convened in 1996 by HHS to identify community preventive programs, services, and policies that increase health and longevity, save lives and dollars, and improve Americans' quality of life. CDC is mandated to provide ongoing administrative, research, and technical support for the operations of the CPSTF. During its meetings, the CPSTF considers the findings of systematic reviews of existing research and practice-based evidence and issues recommendations. CPSTF recommendations are not mandates for compliance or spending. Instead, they provide information about evidence-based options that decision makers and affected community members can consider when they are determining what best meets the specific needs, preferences, available resources, and constraints of their jurisdictions and constituents. The CPSTF's recommendations, along with the systematic reviews of the evidence on which they are based, are compiled on the Community Guide website (*www.thecommunityguide.org*).

Matters proposed for discussion: The agenda will consist of deliberation on systematic reviews of literature. Topics proposed for the October 2024 meeting include substance use, injury prevention, and social determinants of health. Changes regarding the start and end times for each day, and any updates to agenda topics, will be available on the Community Guide website (*www.thecommunityguide.org*) closer to the date of the meeting.

The meeting agenda is subject to change without notice.

Noah Aleshire,

Chief Regulatory Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–20072 Filed 9–5–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–E–1173 and FDA–2019–E–1156]

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

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 STEGLUJAN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission applications 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 November 5, 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 March 5, 2025. 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 November 5, 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 Nos. FDA–2019–E–1173 and FDA–2019–E–1156 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; STEGLUJAN.'' 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. 6200, 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, STEGLUJAN (ertugliflozin and sitagliptin) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both ertugliflozin and sitagliptin is appropriate. Subsequent to this approval, the USPTO received a patent term restoration application for STEGLUJAN (U.S. Patent Nos. 9,308,204 and 9,439,901) from Pfizer Inc., and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated June 12, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of STEGLUJAN 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 STEGLUJAN is 2,976 days. Of this time, 2,610 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* October 28, 2009. The applicant claims October 29, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 28, 2009,

which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 19, 2016. FDA has verified the applicant's claim that the new drug application (NDA) for STEGLUJAN (NDA 209805) was initially submitted on December 19, 2016.

3. *The date the application was approved:* December 19, 2017. FDA has verified the applicant's claim that NDA 209805 was approved on December 19, 2017.

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 applications for patent extension, this applicant seeks 415 days or 424 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: September 3, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20150 Filed 9–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3969]

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—New Drug Application 215244 for Elamipretide Hydrochloride Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Cardiovascular and Renal Drugs Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on October 10, 2024, from 8:15 a.m. to 5:30 p.m. Eastern Time.

ADDRESSES: The public may attend the meeting at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. The public will also have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform.

Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, visitor parking, and transportation, may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2024–N–3969. The docket will close on October 9, 2024. 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 October 9, 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.

Comments received on or before September 26, 2024, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

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–2024–N–3969 for ''Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—New Drug Application 215244 for Elamipretide Hydrochloride Injection.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for