

Panels	Function
<i>Clinical Chemistry and Clinical Toxicology Devices Panel</i>	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine, including clinical toxicology, clinical chemistry, endocrinology and oncology and makes appropriate recommendations to the Commissioner of Food and Drugs.
<i>Immunology Devices Panel</i>	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine, including oncology, immunology, and allergy and makes appropriate recommendations to the Commissioner of Food and Drugs.
<i>Gastroenterology-Urology Devices Panel</i>	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational gastroenterology, urology, and nephrology devices and makes appropriate recommendations to the Commissioner of Food and Drugs.
<i>General Hospital and Personal Use Devices Panel</i>	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational general hospital, infection control and personal use devices and makes appropriate recommendations to the Commissioner of Food and Drugs.
<i>Ophthalmic Devices Panel</i>	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the eye and makes appropriate recommendations to the Commissioner of Food and Drugs.

II. Qualifications

Persons nominated for the device panels should be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers, or have similar appropriate ties to industry.

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current résumés. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for a particular device panel. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

IV. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nomination must include a current, complete résumé or curriculum vitae for each nominee, including current business address and telephone number, email address if available, and a signed copy

of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). Nominations must also specify the advisory panel for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the particular device panels listed in the table. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-14359 Filed 7-5-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-E-2086]

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

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VYEPTI 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 September 6, 2022. 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 January 3, 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. Electronic comments must be submitted on or before September 6, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 6, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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-2020-E-2086 for "Determination of Regulatory Review Period for Purposes of Patent Extension; VYEPTI." 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 biologic 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 VYEPTI (eptinezumab-jjmr). VYEPTI is indicated for the preventive treatment of migraine in adults. Subsequent to this approval, the USPTO received a patent term restoration application for VYEPTI (U.S. Patent No. 9,745,373) from AlderBio Holdings LLC, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 14, 2020, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of VYEPTI 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 VYEPTI is 2,599 days. Of this time, 2,233 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:* January 11, 2013. The applicant claims January 13, 2013, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 11, 2013, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

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):* February 21, 2019. FDA has verified the applicant's claim that the

biologics license application (BLA) for VYEPTI (BLA 761119) was initially submitted on February 21, 2019.

3. *The date the application was approved:* February 21, 2020. FDA has verified the applicant's claim that BLA 761119 was approved on February 21, 2020.

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 637 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: June 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14350 Filed 7–5–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1768]

Advisory Committee; Pharmacy Compounding Advisory Committee; Renewal

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; renewal of federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Pharmacy Compounding Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Pharmacy Compounding Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the April 25, 2024, expiration date.

DATES: Authority for the Pharmacy Compounding Advisory Committee will expire on April 25, 2024, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Takyiah Stevenson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 240–402–2507, PCAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3, FDA is announcing the renewal of the Pharmacy Compounding Advisory Committee (the Committee). The Committee is a non-discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to compounding drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee shall provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a and 353b), and, as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 12 voting members including the Chair. Members and the Chair are selected by the Commissioner or

designee from among authorities knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. These members will include representatives from the National Association of Boards of Pharmacy, the U.S. Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives, or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one or more technically qualified members, selected by the Commissioner or designee, who are identified with consumer interests and are recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one or more non-voting representative members who are identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/pharmacy-compounding-advisory-committee/pharmacy-compounding-advisory-committee-charter> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: June 24, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14346 Filed 7–5–22; 8:45 am]

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