

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, SEGLUROMET (ertugliflozin and metformin hydrochloride) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing ertugliflozin or metformin or in patients who are already treated with both ertugliflozin and metformin. Subsequent to this approval, the USPTO received patent term restoration application for SEGLUROMET (U.S. Patent Nos. 9,308,204 and 9,439,902) from Pfizer Inc., and the USPTO requested FDA's assistance in determining the patents' 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 SEGLUROMET 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 SEGLUROMET 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 SEGLUROMET (NDA 209806) 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 209806 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. 2024–20148 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–2015–D–1580]

Incorporating Voluntary Patient Preference Information Over the Total Product Life Cycle; Guidance for Industry, Food and Drug Administration Staff and Other Interested Parties; 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 the draft guidance entitled “Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle.” This draft guidance explains the principal concepts that sponsors and other interested parties should consider when choosing to collect and submit patient preference information (PPI). The knowledge gleaned from the use of PPI could be used across the total product life cycle, including for review in investigational device exemption (IDE) applications, premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, De Novo classification requests, or premarket notifications (510(k)s). This draft guidance also discusses FDA's inclusion of PPI in its decision summaries and provides recommendations for the inclusion of such information in device labeling for certain devices. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by December 5, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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-2015-D-1580 for “Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle.” 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 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT:

David Gebben, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1316, Silver Spring, MD 20993-0002, 301-796-6461 or James Myers, 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 entitled “Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle.” FDA believes that patients can and should bring their own experiences to bear in helping the Agency to evaluate the benefit-risk profiles of certain devices. This kind of input can be important to consider during FDA’s decision-making for these devices across the total product life cycle.

This draft guidance proposes expanded recommendations to the 2016 guidance entitled “Patient Preference Information—Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling” (2016 PPI Guidance). Since the issuance of the 2016 PPI Guidance, there have been many developments in the use of PPI for devices, including an increase in

industry-sponsored PPI studies provided to FDA for consideration as part of a benefit-risk assessment, and numerous collaborations between FDA scientists and a variety of interested parties to conduct PPI studies to inform clinical trial design and FDA decision making across a wide range of diseases, conditions, and device areas. In addition, FDA has cohosted or participated in numerous convenings and international collaborations to advance scientific methods and practical applications of PPI. Meanwhile, FDA has expanded its benefit-risk guidance framework to apply to the total product life cycle, including the submission and review of IDE applications, 510(k)s, PMAs, De Novo requests, and HDEs applications, and FDA decisions involving administrative, enforcement, and other actions. This expansion of the 2016 PPI Guidance is intended to reflect this broadened scope as well as developments in the field of health preference research.

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 “Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle.” 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. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI01500006 and complete title to

identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new 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 the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
50, 56	Protection of Human Subjects and Institutional Review Boards.	0910–0130

Dated: August 30, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20069 Filed 9–5–24; 8:45 am]

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Dated: August 30, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–20094 Filed 9–5–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; NSC BBA.

Date: October 10, 2024.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, 5601 Fishers Lane, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Bitu Nakhai, Ph.D., Scientific Review Officer, National Institute of Aging, National Institute of Health, 5601 Fishers Lane, 2C212, Rockville, MD 20852, 301–402–7701, nakhaib@nia.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurogenesis and Cell Fate Study Section.

Date: October 2, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Adem Can, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, (301) 435–1042, cana2@csr.nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiology of Eye Disease—1 Study Section Pathophysiology of Eye Disease—1 Study Section (PED1).

Date: October 7–8, 2024.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814 (In-Person Meeting).

Contact Person: Afia Sultana, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4189, Bethesda, MD 20892, (301) 827–7083, sultanaa@mail.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Child Psychopathology and Developmental Disabilities Study Section.

Date: October 7–8, 2024.

Time: 9:00 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michael L. Bloom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7804, Bethesda, MD 20892, 301–451–0132, bloomm2@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; ECHO IDeA States Pediatric Clinical Trials Networks.

Date: October 7–8, 2024.

Time: 3:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Andrew M. Wolfe, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Room 6214, Bethesda, MD 20892, andrew.wolfe@nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333,