

performed on or after January 1, 2024 through December 31, 2024.

FOR FURTHER INFORMATION CONTACT: For clarification of content, please contact Mrs. Autumn King, Policy Analyst, Office of Government-wide Policy, Office of Asset and Transportation Management, at 803-944-6487, or by email at travelpolicy@gsa.gov. Please cite Notice of FTR Bulletin 24-03.

SUPPLEMENTARY INFORMATION: GSA is required by statute to set the mileage reimbursement rate for privately owned automobiles (POA) as the single standard mileage rate established by the Internal Revenue Service (IRS). The IRS mileage rate for medical or moving purposes is used to determine the POA rate when a Government-furnished automobile is available and authorized and also represents the privately owned vehicle (POV) standard mileage reimbursement rate for official relocation.

Finally, GSA conducts independent reviews of the cost of travel and the operation of privately owned airplanes and motorcycles on an annual basis to determine their corresponding mileage reimbursement rates. These reviews evaluate various factors, such as the cost of fuel, depreciation of the original vehicle cost, maintenance and insurance, state and Federal taxes, and consumer price index data. FTR Bulletin 24-03 establishes and announces the new CY 2024 POV mileage reimbursement rates for official temporary duty and relocation travel.

This notice is the only notification to agencies of revisions to the POV mileage rates for official travel and relocation, in addition to the changes posted on GSA's website at <https://gsa.gov/mileage>.

Krystal J. Brumfield,
Associate Administrator, Office of
Government-wide Policy.

[FR Doc. 2023-28563 Filed 12-26-23; 8:45 am]

BILLING CODE 6820-14-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meetings

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of five AHRQ subcommittee meetings.

SUMMARY: The subcommittees listed below are part of AHRQ's Health Services Research Initial Review Group

(IRG) Committee. Grant applications are to be reviewed and discussed at these meetings. Each subcommittee meeting will be closed to the public.

DATES: See below for dates of meetings:

1. *Healthcare Effectiveness and Outcomes Research (HEOR)*
Date: February 7-8, 2024
2. *Healthcare Safety and Quality Improvement Research (HSQR)*
Date: February 7-8, 2024
3. *Health System and Value Research (HSVR)*
Date: February 13-14, 2024
4. *Healthcare Research Training (HCRT)*
Date: February 15-16, 19, 2024
5. *Healthcare Information Technology Research (HITR)*
Date: February 29-March 1, 2024

ADDRESSES: Agency for Healthcare Research and Quality (Virtual Review), 5600 Fishers Lane, Rockville, Maryland, 20857.

FOR FURTHER INFORMATION CONTACT: (to obtain a roster of members, agenda or minutes of the non-confidential portions of the meetings.)

Jenny Griffith, Committee Management Officer, Office of Extramural Research Education and Priority Populations, Division of Policy, Coordination and Analysis, Agency for Healthcare Research and Quality (AHRQ), 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 427-1557.

SUPPLEMENTARY INFORMATION: In accordance with section 10 (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), AHRQ announces meetings of the above-listed scientific peer review groups, which are subcommittees of AHRQ's Health Services Research Initial Review Group Committee. The subcommittee meetings will be closed to the public in accordance with the provisions set forth in 5 U.S.C. app. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6). 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.

Agenda items for these meetings are subject to change as priorities dictate.

Dated: December 20, 2023.

Marquita Cullom,
Associate Director.

[FR Doc. 2023-28506 Filed 12-26-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2022-E-0931 and FDA-2022-E-0936]

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

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 ZOKINVY 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 patents 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 26, 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 24, 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 26, 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-2022-E-0931 and FDA-2022-E-0936 for "Determination of Regulatory Review Period for Purposes of Patent Extension; ZOKINVY." 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 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 ZOKINVY (lonafarnib). ZOKINVY is indicated in patients 12 months of age and older with a body surface area of 0.39 m² and above to reduce risk of mortality in Hutchinson-Gilford Progeria Syndrome; and for treatment of processing-deficient Progeroid Laminopathies with either Heterozygous *LMNA* mutation with progerin-like protein accumulation or Homozygous or compound heterozygous *ZMPSTE24* mutations.

Subsequent to this approval, the USPTO received a patent term restoration application for ZOKINVY (U.S. Patent Nos. 7,838,531 and 8,828,356) from the Government of the United States of America as represented by the Department of Health and Human Services; the Regents of the University of Michigan; Progeria Research Foundation, Inc.; and the University of North Carolina at Chapel Hill, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated November 9, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ZOKINVY 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 ZOKINVY is 5,023 days. Of this time, 4,777 days occurred during the testing phase of the regulatory review period, while 246 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:* February 21, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 21, 2007.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* March 20, 2020. FDA has verified the applicant's claim that

the new drug application (NDA) for ZOKINVY (NDA 213969) was initially submitted on March 20, 2020.

3. *The date the application was approved:* November 20, 2020. FDA has verified the applicant's claim that NDA 213969 was approved on November 20, 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 applications for patent extension, this applicant seeks 1,255 days or 1,948 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 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28511 Filed 12–26–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–E–2035]

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

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 PONVORY 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 26, 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 24, 2024. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

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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>.

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