

required to notify FDA, when such notifications are required, what information FDA expects manufacturers to include in such notifications, and how to submit notifications.

Additionally, FDA describes how FDA determines that a device is in shortage and additional actions FDA may take to help prevent or mitigate a potential device shortage.

In the draft guidance “Select Updates for the 506J Guidance: 506J Device List and Additional Notifications,” FDA proposes updates to the 506J Guidance. Specifically, FDA has developed a list of devices, by FDA product code, for which a manufacturer of such devices is required to notify FDA in accordance with section 506J (hereafter referred to as the “506J Device List”). The 506J Device List is based on the requirements

under section 506J(a) of the FD&C Act. In section 2514 of the FY 2023 Omnibus, Congress directed FDA to issue guidance on the requirements under section 506J and to include “a list of each device product code for which a manufacturer of such device is required to notify the Secretary in accordance with section 506J.” Thus, manufacturers of a device on the 506J Device List must notify FDA in accordance with 506J for each such device. For more information, manufacturers should see the 506J Device List web page, available at <https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/506j-device-list>. Additionally, consistent with section 506J(h), FDA is proposing to clarify for stakeholders that manufacturers may submit, and FDA

may receive, voluntary notifications regarding supply chain issues at any time, unrelated to the declaration or potential declaration of a PHE.

The guidance documents include additional voluntary items that manufacturers could provide the Agency, including additional information about device manufacturing and supply, and updates to initial notifications.

Respondents may notify FDA about an interruption or permanent discontinuance in device manufacturing (506J notification) on our website at <https://fda-cdrh.my.salesforce-sites.com/shortages/>.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Shortages outreach data collection	1,000	4	4,000	1	4,000
Information collection under section 506J	8,400	1	8,400	0.25 (15 minutes)	2,100
Additional voluntary collections related to section 506J	8,400	1	8,400	0.25 (15 minutes)	2,100
Total			20,800		8,200

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

I. Shortages Outreach Data Collection

FDA bases these estimates on our recent experience and informal direct contact with respondents. We estimate up to 1,000 manufacturers, distributors, healthcare systems, healthcare providers, group purchasing organizations, and sterilizers for which there may be targeted outreach because their devices may be essential to the response effort. This targeted outreach will be conducted periodically either to obtain primary data or to verify/validate updated data (although additional outreach may be undertaken as needed). The data being requested represent common data elements that respondents monitor and track as part of routine business operations and, therefore, are readily available. It is anticipated that for most respondents, the estimated time to fulfill CDRH’s data request will not exceed 1 hour per request, or 4 hours per year.

II. Information Collection Under Section 506J of the FD&C Act and Related Voluntary Collections

Based on current registration and listing data (approved under OMB control number 0910–0625), we estimate the number of respondents that will submit a notification under section 506J of the FD&C Act to be approximately 20 percent of currently

registered manufacturers. Data from our Registration and Listing system indicate that there are approximately 42,000 unique FDA Establishment Identification registered manufacturers. Therefore, we estimate 8,400 respondents per year. We believe that the burden, including the provision of required information under section 506J of the FD&C Act, as well as additional voluntary information (including additional issues that may impact the availability of the device, such as information about critical suppliers, potential mitigations, production capacity and market share, and notification updates), is minimal and such information is readily available to respondents. Therefore, we estimate the burden of this information collection to be 15 minutes or less per notification.

Since the last OMB approval, we have updated the Number of Respondents and Average Burden per Response for the Shortages Outreach Data Collection element based on our recent experience with the information collection and informal direct contact with respondents. The updates result in an adjustment of an additional 3,000 hours and 2,000 responses annually.

Dated: November 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26199 Filed 11–27–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–E–2101]

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

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 Korsuva 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 January 29, 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 May 28, 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 January 29, 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-2022-E-2101 for “Determination of Regulatory Review Period for Purposes of Patent Extension; KORSUVA.” 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, Korsuva (difelikefalin acetate). Korsuva is indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis. Subsequent to this approval, the USPTO received a patent term restoration application for Korsuva (U.S. Patent No. 7,402,564) from Cara Therapeutics, Inc., and the USPTO requested FDA’s assistance in determining the patent’s eligibility for patent term restoration. In a letter dated September 28, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of Korsuva 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 Korsuva is 4,625 days. Of this time, 4,381 days occurred during the testing phase of the regulatory review period, while 244 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:* December 26, 2008. The applicant claims January 16, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 26, 2008, 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 23, 2020. FDA has verified the applicant's claim that the new drug application (NDA) for Korsuva (NDA 214916) was initially submitted on December 23, 2020.

3. *The date the application was approved:* August 23, 2021. FDA has verified the applicant's claim that NDA 214916 was approved on August 23, 2021.

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 1,827 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: November 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26106 Filed 11–27–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–2188 and FDA–2022–E–2189]

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

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 Tavneos and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claim that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by January 29, 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 May 28, 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 January 29, 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.

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- 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”).

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- 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–2188 and FDA–2022–E–2189 for “Determination of Regulatory Review Period for Purposes of Patent Extension; TAVNEOS.” 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.