

9, 2025 (90 FR 43445). OGE received one set of comments containing several recommendations. OGE appreciates the feedback and considered each recommendation. The proposed modifications discussed below incorporate recommendations received that OGE believes will increase clarity, improve user experience, and/or reduce the burden on requesters utilizing the form. OGE declined to adopt other recommendations because they could not be implemented due to technical limitations, the suggested course of action fell outside of the scope of the form renewal process, or because OGE reached a different conclusion than the commenter regarding the utility of the specific form inquiry on which action was recommended.

Proposed changes to the PDF and online English language versions:

- Modifying the language of the Privacy Act Statement for clarity.
 - Modifying the Ethics in Government Act citation for accuracy.
- Proposed changes to the PDF version only:*

- Adding language to the Supplemental Information section to (1) better capture the full scope of records available from OGE upon request and (2) inform requesters of general retention periods that may impact the availability of the documents they are requesting.

- Removing the following text from the “Should I use the online system or fill out the PDF Form?” portion of the Supplemental Information section because it is no longer relevant: “Note: Currently OGE is unable to fill any request using the PDF Form that does not provide an email address for the requestor.”

- Replacing sub-section numbering with standard numbering to improve user experience.

- Adding a parenthetical containing the word “optional” next to the “Your telephone number” section heading to clarify that providing such information is optional.

- Combining sections 1a and 6 into a single section with updated language (section 2 of proposed form) to reduce the number of responses needed to complete the form and explain why the requested information is sought.

- Relocating section 4 on page 3 of the current form down to section 8 of the proposed form and adding an explanatory parenthetical clarifying that a response is optional and informing that the requested information is for statistical purposes only.

- Combining sections 5 and 5a into a single section (section 7 of proposed form), updating the language of that

section to better align it with the requirements of the Ethics in Government Act, and adding language to inform that documents are generally retained for 6 to 7 years under Federal law such that older documents may not be available.

- Updating the language of the form’s Continuation Page to align it with section 7 of the proposed form, discussed above.

- Modifying text, formatting and spacing in several places to improve accuracy, clarity, consistency, and/or alignment with plain language principles.

To view a draft of the pdf version with proposed changes, visit the download link at [https://www.oge.gov/Web/OGEnsf/0/912FAA19EB55D09185258D940067A5AC/\\$FILE/OGE%20Form%20201%20RenewalDraft_2nd%20Round%20FR%20\(Feb\)_.pdf](https://www.oge.gov/Web/OGEnsf/0/912FAA19EB55D09185258D940067A5AC/$FILE/OGE%20Form%20201%20RenewalDraft_2nd%20Round%20FR%20(Feb)_.pdf).

Proposed removal of the translated online versions of the form: Because OGE does not have the resources available to update its translated online versions of the form, OGE is proposing to remove the Arabic, Chinese, French and Spanish language versions of its Form 201 online application.

Request for Comments: Agency and public comment are invited specifically on the need for and practical utility of this information collection, the accuracy of OGE’s burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). Comments received in response to this notice will be summarized for and included with the OGE request for extension of OMB paperwork approval. The comments will also become a matter of public record.

Specifically, OGE seeks public comment on the following:

- What problems do you have using the form?
- Are there sections of the form or instructions that are unclear?
- Is there information provided that is confusing?
- What additional information would be helpful?

Authority: 44 U.S.C. 3501 *et seq.*; 5 U.S.C. 13107(b) and (c); 5 U.S.C. 13122(b)(1); 5 CFR 2634.603(c) and (f).

Approved: February 27, 2026.

James Cooper,
Chief Information Officer, Office of Government Ethics.

[FR Doc. 2026–04439 Filed 3–5–26; 8:45 am]

BILLING CODE 6345–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–E–0493]

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

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 ENSACOVE 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 May 5, 2026. 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 September 2, 2026. 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 May 5, 2026. 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-2025-E-0493 for "Determination of Regulatory Review Period for Purposes of Patent Extension; ENSACOVE." 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: Jack Dan, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240-402-6940.

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, ENSACOVE (ensartinib). ENSACOVE is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer who have not previously received an ALK-inhibitor. Subsequent to this approval, the USPTO received a patent term restoration application for ENSACOVE (U.S. Patent No. 9,126,947) from Xcovery Holdings, Inc. and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 8, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ENSACOVE 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 ENSACOVE is 4,645 days. Of this time, 4,288 days occurred during the testing phase of the regulatory review period, while 357 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:* April 2, 2012. The applicant claims April 4, 2012, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 2, 2012, 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 drug product under section 505 of the FD&C Act:* December 28, 2023. FDA has verified the applicant's claim that the new drug application (NDA) for ENSACOVE (NDA 218171) was initially submitted on December 28, 2023.

3. *The date the application was approved:* December 18, 2024. FDA has verified the applicant's claim that NDA

218171 was approved on December 18, 2024.

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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–04491 Filed 3–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–1001]

Developing Specifications for In-Home Disposal Systems for Opioid Analgesics Dispensed in an Outpatient Setting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the establishment of a docket to solicit public comment on what specifications for in-home disposal systems, if application holders are required to make them available under the Opioid Analgesic Risk Evaluation and Mitigation Strategy, would be necessary to show that these systems may mitigate the serious risks of abuse or overdose involving these medications.

DATES: Submit either electronic or written comments by April 6, 2026.

ADDRESSES: FDA is establishing a docket for public comment on this notice. The docket number is FDA–2026–N–1001. The docket will close on April 6, 2026. Submit either electronic or written comments by April 6, 2026. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 6, 2026. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 6, 2026. 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.

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”).

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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 No. FDA–2026–N–1001 for “Developing Specifications for In-Home Disposal Systems That May Be Made Available Through the Opioid Analgesic Risk Evaluation and Mitigation Strategy For Opioid Analgesics Dispensed in an Outpatient Setting; Establishment of a Public Docket; Request for Comments” 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.

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