TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR part FDA form number	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
807.22(b)(3)[3] Annual Update of Listing Information (FDA 3673)	28,925	1	28,925	0.5	14,463
807.22(b)(4) Changes to listing information (outside of annual listing requirement period):					
Voluntary reporting of transfer of 510(k) clearance in FURLS (outside of annual listing requirement period)	4,080	1	4,080	0.25	1,020
Submission of 510(k) transfer documentation when more than one party lists the same 510(k)	2,033	1	2,033	4	8,132
807.26(e)[3] Labeling & Advertisement Submitted at FDA Request	1	1	1	1	1
807.34(a)[2] Initial Registration & Listing when Electronic Filing Waiver Granted	1	1	1	1	1
807.34(a)[3] Annual Registration & Listing when Electronic Filing Waiver granted	1	1	1	1	1
807.40(b)(2)[3] Annual Update of US Agent Information (FDA 3673)	3,410	1	3,410	0.5	1,705
807.40(b)(3)[3] US Agent Responses to FDA Requests for Information (FDA 3673)	1,535	1	1,535	0.25	384
807.41(a)[3] Identification of initial importers defined in 21 CFR 807.3(g) by foreign establishments (FDA 3673)	2,955	1	2,955	0.5	1,478
807.41(b)[3] Identification of other importers (defined in 21 CFR 807.3(x) and (y) that facilitate import by foreign establishments (FDA 3673)	3,234	1	3,234	0.5	1,617
Total					56,546

[1] Totals are rounded to the nearest whole number.
[2] One Time Burden—Firm only provides initially.
[3] Recurring Burden—Firm is required to review annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
807.25(d)[2] List of Officers, Directors & Partners	22,338	1	22,338	.25	5,585
807.26[2] Labeling & Advertisements Available for Review	17,032	4	68,128	.5	34,064
Total					39,649

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Recurring burden—Firm is required to keep records.

Our estimated burden for the information collection reflects an overall decrease of 17,637 hours and a corresponding decrease of 34,530 responses/records. Burden estimates are based on recent registration and listing information collected from establishments registering for the first time (initial registration) and establishments re-registering. We attribute this adjustment to a decrease in the number of submissions we received over the last approval period.

Dated: June 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11312 Filed 6–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–E–0211]

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

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 JOENJA 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 August 19, 2025. 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 December 17, 2025. 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 August 19, 2025. 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–2024–E–0211 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; JOENJA.'' 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, 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, JOENJA (leniolisib phosphate) indicated for the treatment of activated phosphoinositide 3-kinase delta syndrome in adult and pediatric patients 12 years of age and older. Subsequent to this approval, the USPTO received a patent term restoration application for JOENJA (U.S. Patent No. 8,653,092) from Novartis AG and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated February 7, 2024, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of JOENJA 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 JOENJA is 3,900 days. Of this time, 3,661 days occurred during the testing phase of the regulatory review period, while 239 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:* July 21, 2012. The applicant claims January 20, 2015, as the date the investigational new drug

application (IND) became effective. However, FDA records indicate that the IND effective date was July 21, 2012, which was 30 days after FDA receipt of an earlier IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* July 29, 2022. FDA has verified the applicant's claim that the new drug application (NDA) for JOENJA (NDA 217759) was initially submitted on July 29, 2022.

3. *The date the application was approved:* March 24, 2023. FDA has verified the applicant's claim that NDA 217759 was approved on March 24, 2023.

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 1,613 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 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11318 Filed 6–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5338]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Interstate Shellfish Dealer's Certificate and Participation in the National Shellfish Sanitation Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by July 21, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0021. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Interstate Shellfish Dealer's Certificate and Participation in the National Shellfish Sanitary Program

OMB Control Number 0910–0021—Revision

Under section 243 of the Public Health Service Act (PHS Act) (42 U.S.C. 243), FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the U.S. bivalve molluscan shellfish industry in the NSSP.

Molluscan shellfish consumed fresh (raw) and fresh frozen poses unique public health concerns. The safety of molluscan shellfish directly reflects the cleanliness of the waters where they are grown. Molluscan shellfish are sessile, filter-feeding organisms that pump large quantities of water through their bodies during their normal feeding process. The relationship between shellfish harvesting waters that are contaminated with sewage and other forms of pollution and food safety concerns has been demonstrated often. Additionally, bivalve molluscan shellfish must be held, packed, and shipped under sanitary conditions to prevent contamination subsequent to harvest and prior to delivery to the consumer.

The NSSP is a voluntary cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish dealers. Each participating State and foreign nation monitors its molluscan shellfish production and issues certificates for those dealers that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish dealers to FDA on Form FDA 3038, ''Interstate Shellfish Dealer's Certificate'' (available for download at *https://www.fda.gov/media/72094/download*). FDA uses this information to publish the ''Interstate Certified Shellfish Shippers List (ICSSL),'' a monthly comprehensive listing of all molluscan shellfish dealers certified under the cooperative program (available at *https://www.fda.gov/food/federalstate-food-programs/interstate-certified-shellfish-shippers-list*). We also provide information on our website at *https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/state-cooperative-programs/fda-national-shellfish-sanitation-program,* which may serve as a helpful resource to respondents.

Under the authority of section 243 of the PHS Act, we are revising this information collection to also collect from State regulatory agencies samples of shellfish, along with metadata (date collected, temperature, and location). If available, we are also collecting analytical results needed to classify growing area waters for existing and emerging food safety hazards and to ensure that shellfish products of dealers