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, BALVERSA (erdafitinib) indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 or FGFR2 genetic alterations and progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy. Patients are selected for therapy based on an FDA-approved companion diagnostic for BALVERSA. This indication is approved under accelerated approval based on tumor response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Subsequent to this approval, the USPTO received a patent term restoration application for BALVERSA (U.S. Patent No. 8,895,601) from Astex Therapeutics Ltd. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated January 4, 2021, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of BALVERSA 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 BALVERSA is 2,179 days. Of this time, 1,972 days occurred during the testing phase of the regulatory review period, while 207 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 26, 2013. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 26, 2013.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* September 18, 2018. FDA has verified the applicant's claim that the new drug application (NDA) for BALVERSA (NDA 212018) was initially submitted on September 18, 2018.

3. *The date the application was approved:* April 12, 2019. FDA has verified the applicant's claim that NDA 212018 was approved on April 12, 2019.

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 691 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 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13973 Filed 6–29–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1207]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Plant Varieties Intended for Food Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 30, 2021.

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 0910–0583. 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.

New Plant Varieties Intended for Food Use

OMB Control Number 0910–0583—Revision

This information collection supports recommendations found in Agency guidance pertaining to new plant varieties intended for food use. Respondents to the collection of information are developers of new plant varieties intended for food use.

I. Consultation Procedures: Foods Derived From New Plant Varieties; Form FDA 3665

The Agency guidance document entitled ''Guidance on Consultation Procedures: Foods Derived From New Plant Varieties,'' which is available on our website at *https://www.fda.gov/FoodGuidances,* describes our consultation process for the evaluation of information on new plant varieties provided by developers. We believe this consultation process will help ensure that human and animal food safety issues or other regulatory issues (*e.g.,* labeling) are resolved prior to commercial distribution. Additionally, such communication will help to ensure that any potential food safety issues regarding a new plant variety are resolved during development and will help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the standards of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Since 1992, when FDA issued its ''Statement of Policy: Foods Derived From New Plant Varieties'' (the 1992 policy) (57 FR 22984, May 29, 1992), we have encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with FDA during the plant development process to discuss possible scientific and regulatory issues that might arise. In the 1992 policy, we explained that under the FD&C Act developers of new foods (in this document food refers to both human and animal food) have a responsibility to ensure that the foods they offer to consumers are safe and in compliance with all requirements of the FD&C Act (57 FR 22984 at 22985). Respondents may use Form FDA 3665, submitted via the Electronic Submissions Gateway (*https://www.fda.gov/industry/electronic-submissions-gateway*), to request consultation.

II. Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Form FDA 3666

Since May 29, 1992, when we issued a policy statement on foods derived from new plant varieties, including those varieties that are developed through biotechnology, we have encouraged developers of new plant varieties to consult with us early in the development process to discuss possible scientific and regulatory issues that might arise (57 FR 22984). The guidance entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recommendations-early-food-safety-evaluation-new-non-pesticidal-proteins-produced*) continues to foster early communication by encouraging developers to submit to us their evaluation of the food safety of their new proteins. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of the new protein.

We believe that any food safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin. The guidance describes the procedures for early food safety evaluation of new proteins produced by new plant varieties, including bioengineered food plants, and the procedures for communicating with us about the safety evaluation.

Interested persons may use Form FDA 3666 to transmit their submission to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition (CFSAN). Form FDA 3666 is entitled ''Early Food Safety Evaluation of a New Non-Pesticidal Protein Produced by a New Plant Variety (New Protein Consultation)'' and may be used in lieu of a cover letter for a New Protein Consultation (NPC). The form may be accessed at FDA's web page for forms (*https://www.fda.gov/about-fda/reports-manuals-forms/forms*) using the search term ''3666.'' To enable field-fillable functionality of FDA forms, they must be downloaded. Form FDA 3666 prompts a submitter to include certain elements of an NPC in a standard format and helps the respondent organize their submission to focus on the information needed for our safety review. The form, and elements prepared as attachments to the form, may be prepared using the CFSAN Online Submission Module (*https://www.fda.gov/food/registration-food-facilities-and-other-submissions/cfsan-online-submission-module-cosm*). Once the submission is prepared, it may be submitted in electronic format via the Electronic Submissions Gateway (*https://www.fda.gov/industry/electronic-submissions-gateway*), paper format, or as electronic files on physical media with paper signature page.

In the **Federal Register** of November 23, 2020 (85 FR 74734), we published a 60-day notice requesting public comment on information collection associated with the guidance document ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use.'' No comments were received.

In the **Federal Register** of March 4, 2021 (86 FR 12688), we published a 60-day notice requesting public comment on information collection associated with the guidance document ''Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use.'' No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Agency guidance recommendations; information collection	Form FDA No.	Number of responses	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Consultation Procedures: Foods Derived From New Plant Varieties						
Initial consultation	None	20	2	40	4	160
Final consultation	3665	12	1	12	150	1,800
Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use						
First four data components	3666	6	1	6	4	24
Two other data components	3666	6	1	6	16	96

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Agency guidance recommendations; information collection	Form FDA No.	Number of responses	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total				64		2,080

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

For efficiency of Agency operations, we are consolidating these related information collections. We retain our estimate of burden associated with the individual collection activities but have increased burden in OMB control number 0910–0583 by 52 responses and 1,960 hours annually to reflect the reorganization of the information collection. Upon OMB approval of our request, we intend to discontinue OMB control number 0910–0704.

Dated: June 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13953 Filed 6–29–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–2192; FDA–2020–E–2194; FDA–2020–E–2195]

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

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 OXBRYTA 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 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 30, 2021. 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 27, 2021. 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. Electronic comments must be submitted on or before August 30, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 30, 2021. 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.

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–2020–E–2192; FDA–2020–E–2194; and FDA–2020–E–2195, for ''Determination of Regulatory Review Period for Purposes of Patent Extension; OXBRYTA.'' 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.*