Therefore, approval of the applications listed in the table and all amendments and supplements thereto, are hereby withdrawn as of March 14, 2019. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on March 14, 2019 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: February 7, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02032 Filed 2–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0294]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Contact Substance Notification 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: Fax written comments on the collection of information by March 14, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0495. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Food Contact Substance Notification Program—21 CFR 170.101, 170.106, and 171.1

OMB Control Number 0910–0495—Extension

This information collection supports FDA regulations regarding Food Contact Substance Notification, as well as associated guidance and accompanying forms. Section 409(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(h)) establishes a premarket notification process for food contact substances. Section 409(h)(6) of the FD&C Act defines a ''food contact substance'' as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' Section 409(h)(3) of the FD&C Act requires that the notification process be used for authorizing the marketing of food contact substances except when: (1) We determine that the submission and premarket review of a food additive petition (FAP) under section 409(b) of the FD&C Act is necessary to provide adequate assurance of safety or (2) we and the manufacturer or supplier agree that an FAP should be submitted. Section 409(h)(1) of the FD&C Act requires that a notification include: (1) Information on the identity and the intended use of the food contact substance and (2) the basis for the manufacturer's or supplier's determination that the food contact substance is safe under the intended conditions of use.

Sections 170.101 and 170.106 of FDA's regulations (21 CFR 170.101 and 170.106) specify the information that a notification must contain and require that: (1) A food contact substance notification (FCN) includes Form FDA 3480 and (2) a notification for a food contact substance formulation includes Form FDA 3479. These forms serve to summarize pertinent information in the notification. The forms facilitate both preparation and review of notifications because the forms will serve to organize information necessary to support the safety of the use of the food contact substance. The burden of filling out the appropriate form has been included in the burden estimate for the notification.

Currently, interested persons transmit an FCN submission to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition using Form FDA 3480 whether it is submitted in electronic or paper format. We estimate that the amount of time for respondents to complete Form FDA 3480 will continue to be the same.

In addition to its required use with FCNs, Form FDA 3480 is recommended to be used to organize information within a Pre-notification Consultation or Master File submitted in support of an FCN according to the items listed on the form. Master Files can be used as repositories for information that can be referenced in multiple submissions to FDA, thus minimizing paperwork burden for food contact substance authorizations. We estimate that the amount of time for respondents to complete the Form FDA 3480 for these types of submissions is 0.5 hours.

FDA recommends using Form FDA 3480A for each submission of additional information (*i.e.,* amendment) to an FCN submission currently under Agency review. Form FDA 3480A helps the respondent organize the submission to focus on the information needed for FDA's safety review.

FDA's guidance documents entitled: (1) ''Preparation of Food Contact Notifications: Administrative,'' (2) ''Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations,'' and (3) ''Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations'' provide assistance to industry regarding the preparation of an FCN and a petition for a food contact substances (FCSs). FDA has also developed a draft guidance entitled, ''Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk.'' Once finalized, the guidance will provide our current thinking on how to prepare an FCN for FDA review and evaluation of the safety of FCSs used in contact with infant formula and/or human milk. These guidances are available at *https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/default.htm.*

Section 171.1 of FDA's regulations (21 CFR 171.1) specifies the information that a petitioner must submit in order to: (1) Establish that the proposed use of an indirect food additive is safe and (2) secure the publication of an indirect

food additive regulation in parts 175 through 178 (21 CFR parts 175 through 178). Parts 175 through 178 describe the conditions under which the additive may be safely used.

In addition, the guidance entitled ''Use of Recycled Plastics in Food Packaging: Chemistry Considerations,'' provides assistance to manufacturers of food packaging in evaluating processes for producing packaging from post-consumer recycled plastic. The recommendations in the guidance address the process by which manufacturers certify to us that their plastic products are safe for food contact.

Description of Respondents: The respondents to this information collection are manufacturers of food contact substances sold in the United States. Respondents are from the private sector (for-profit businesses).

In the **Federal Register** of September 13, 2018 (83 FR 46493), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received unrelated to the information collection and therefore is not discussed here.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section; Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
170.106 [2] (Category A)	FDA 3479	10	2	20	2	40
170.101 [3] [7] (Category B)	FDA 3480	6	1	6	25	150
170.101 [4] [7] (Category C)	FDA 3480	6	2	12	120	1,440
170.101 [5] [7] (Category D)	FDA 3480	42	2	84	150	12,600
170.101 [6] [7] (Category E)	FDA 3480	38	1	38	150	5,700
Pre-notification Consultation or Master File (concerning a food contact substance) [8].	FDA 3480	190	1	190	0.5 (30 minutes).	95
Amendment to an existing notification (170.101), amendment to a Pre-notification Consultation, or amendment to a Master File (concerning a food contact substance) [9].	FDA 3480A	100	1	100	0.5 (30 minutes).	50
171.1 Indirect Food Additive Petitions	N/A	1	1	1	10,995	10,995
Use of Recycled Plastics in Food Packaging: Chemistry Considerations.	N/A	10	1	10	25	250
Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk.		2	1	2	5	10
Total						31,330

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Notifications for food contact substance formulations and food contact articles. These notifications require the submission of Form FDA 3479 (''Notification for a Food Contact Substance Formulation'') only.
[3] Duplicate notifications for uses of food contact substances.
[4] Notifications for uses that are the subject of exemptions under 21 CFR 170.39 and very simple food additive petitions.
[5] Notifications for uses that are the subject of moderately complex food additive petitions.
[6] Notifications for uses that are the subject of very complex food additive petitions.
[7] These notifications require the submission of Form FDA 3480.
[8] These notifications recommend the submission of Form FDA 3480.
[9] These notifications recommend the submission of Form FDA 3480A.

The estimates are based on our current experience with the Food Contact Substance Notification Program and informal communication with industry. Our estimated burden for the information collection reflects an overall increase of 10 hours and a corresponding increase of 2 responses from the currently approved burden. We attribute this adjustment to reviewing and submitting FCNs consistent to the draft guidance entitled, ''Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk.''

Beginning in row 1, we estimate 10 respondents will submit 2 notifications annually for food contact substance formulations (Form FDA 3479), for a total of 20 responses. We calculate a reporting burden of 2 hours per response, for a total of 40 hours. In row 2 we estimate six respondents. We believe the hourly burden for preparing these notifications will primarily consist of the manufacturer or supplier completing Form FDA 3480, verifying that a previous notification is effective and preparing necessary documentation. We estimate one submission for each respondent, for a total of six responses. We calculate a reporting burden of 25 hours per response, for a total of 150 hours.

In rows 3, 4, and 5, we identify three tiers of FCNs that reflect different levels of burden applicable to the respective information collection items (denoted as Categories C, D, and E). We estimate 6 respondents will submit 2 Category C submissions annually, for a total of 12 responses. We calculate a reporting burden of 120 hours per response, for a total burden of 1,440 hours. We estimate 42 respondents will submit 2 Category D submissions annually, for a total of 84 responses. We calculate a reporting burden of 150 hours per response, for a total burden of 12,600 hours. We estimate 38 respondents will submit 1 Category E submission annually, for a total of 38 responses. We calculate a reporting burden of 150 hours per response, for a total burden of 5,700 hours.

In row 6, we estimate 190 respondents will submit information to a pre-notification consultation or a master file in support of FCN submission using Form FDA 3480. We calculate a reporting burden of 0.5 hours per response, for a total burden of 95 hours. In row 7 we estimate 100 respondents will submit an amendment (Form FDA 3480A) to a substantive or non-substantive request of additional

information to an incomplete FCN submission, an amendment to a pre-notification consultation, or an amendment to a master file in support of an FCN. We calculate a reporting burden of 0.5 hours per response, for a total burden of 50 hours.

In row 8, we estimate one respondent will submit one indirect food additive petition under § 171.1, for a total of one response. We calculate a reporting burden of 10,995 hours per response, for a total burden of 10,995 hours.

In row 9, we estimate 10 respondents will utilize the recommendations in the guidance document entitled, ''Use of Recycled Plastics in Food Packaging: Chemistry Considerations,'' to develop the additional information for one such submission annually, for a total of 10 responses. We calculate a reporting burden of 25 hours per response, for a total burden of 250 hours.

Finally, in row 10, we estimate 2 respondents will utilize the recommendations in the draft guidance, once finalized, entitled, ''Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk,'' to develop the additional information for one such submission annually, for a total of 2 responses. We calculate a reporting burden of 5 hours per response, for a total burden of 10 hours.

Dated: February 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01977 Filed 2–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–E–6739]

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

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 ZEJULA 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 the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 15, 2019. 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 August 12, 2019. 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 April 15, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 15, 2019. 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 No. FDA–2017–E–6739 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ZEJULA.'' 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.

- 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.gpo.gov/fdsys/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