

data collection duration for the same facility types during the 2013–2014 data collection. FDA estimates that it will take the persons in charge of full service restaurants and fast food restaurants 104 minutes (1.73 hours) and 82 minutes (1.36 hours), respectively, to accompany the data collectors while they complete Sections 1 and 3 of the form. In comparison, for the 2013–2014 data collection, the burden estimate was 106 minutes (1.76 hours) in full service restaurants and 73 minutes (1.21 hours) in fast food restaurants. FDA estimates that it will take the program director (or

designated individual) of the respective regulatory authority 30 minutes (0.5 hours) to answer the questions related to Section 2 of the form. This burden estimate is unchanged from the last data collection. Hence, the total burden estimate for a data collection in a full service restaurant, including the responses of both the program director and the person in charge, is 134 minutes (104 + 30) (2.23 hours). The total burden estimate for a data collection in a fast food restaurant, including the responses of both the program director and the

person in charge, is 112 minutes (82 + 30) (1.86 hours).

Based on the number of entry refusals from the 2013–2014 baseline data collection, we estimate a refusal rate of 2 percent for the data collections within restaurant facility types. The estimate of the time per non-respondent is 5 minutes (0.08 hours) for the person in charge to listen to the purpose of the visit and provide a verbal refusal of entry.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Number of non-respondents	Number of responses per non-respondent	Total annual non-responses	Average burden per response	Total hours
2021–2022 Data Collection (Fast Food Restaurants)—Completion of Sections 1 and 3.	400	1	400	.....	.....	.....	1.36 .....	544
2021–2022 Data Collection (Full Service Restaurants)—Completion of Sections 1 and 3.	400	1	400	.....	.....	.....	1.73 .....	692
2021–2022 Data Collection—Completion of Section 2—All Facility Types.	800	1	800	.....	.....	.....	0.5 (30 minutes) .....	400
2021–2022 Data Collection—Entry Refusals—All Facility Types.	—	—	—	16	1	16	0.08 (5 minutes) .....	1.28
<b>Total Hours</b> .....	.....	.....	.....	.....	.....	.....	.....	1,637.28

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

The burden for this information collection has not changed since the last OMB approval.

**II. References**

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday, they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. “Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors” (2000). Available at: <https://wayback.archive-it.org/7993/20170406023019/https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf>.

2. “FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and

Retail Food Store Facility Types (2004).” Available at: <https://wayback.archive-it.org/7993/20170406023011/https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf>.

3. “FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009).” Available at: <https://wayback.archive-it.org/7993/20170406023004/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm224321.htm>.

4. FDA National Retail Food Team. “FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998–2008).” Available at: <https://wayback.archive-it.org/7993/20170406022950/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm223293.htm>.

5. “FDA Food Code.” Available at: <https://www.fda.gov/FoodCode>.

Dated: January 31, 2018.

**Leslie Kux,**  
Associate Commissioner for Policy.  
[FR Doc. 2018–02414 Filed 2–6–18; 8:45 am]  
**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA–2015–E–0857 and FDA–2015–E–0858]

**Determination of Regulatory Review Period for Purposes of Patent Extension; FARXIGA**

**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 FARXIGA 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 (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 9, 2018. 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 9, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 9, 2018. 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. 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 6, 2018. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

#### 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–2015–E–0857 and FDA–2015–E–0858 for “Determination of Regulatory Review Period for Purposes of Patent Extension; FARXIGA.” 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 Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**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 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 FARXIGA (dapagliflozin). FARXIGA is indicated as an adjunct to diet and exercise to

improve glycemic control in adults with type 2 diabetes mellitus. Subsequent to this approval, the USPTO received patent term restoration applications for FARXIGA (U.S. Patent Nos. 6,414,126 and 6,515,117) from AstraZeneca AB, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated October 19, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of FARXIGA 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 FARXIGA is 3,673 days. Of this time, 2,565 days occurred during the testing phase of the regulatory review period, while 1,108 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* December 21, 2003. FDA has verified the AstraZeneca AB claim that the date the investigational new drug application became effective was on December 21, 2003.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 28, 2010. The applicant claims December 27, 2010, as the date the new drug application (NDA) for FARXIGA (NDA 202293) was initially submitted. However, FDA records indicate that NDA 202293 was submitted on December 28, 2010.

3. *The date the application was approved:* January 8, 2014. FDA has verified the applicant's claim that NDA 202293 was approved on January 8, 2014.

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 applications for patent extension, this applicant seeks 1,825 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–2018–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: January 31, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–02418 Filed 2–6–18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–N–0074]

### Agency Information Collection Activities; Proposed Collection; Comment Request; State Enforcement Notifications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA regulations governing State enforcement notifications.

**DATES:** Submit either electronic or written comments on the collection of information by April 9, 2018.

**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 9, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 9, 2018. 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–2018–N–0074 for “State Enforcement