federal IT platform (*i.e.,* HealthCare.gov). HHS anticipates that consumers may use this information to inform plan selection.

As stated in the final rule Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310; March 27, 2012), broader implementation will continue to be addressed in separate rulemaking issued by HHS, and the Departments of Labor and the Treasury (the Departments).

Consistent with Public Health Service Act (PHS Act) [1] section 2715A, which largely extends the transparency reporting provisions set forth in section 1311(e)(3) to non-grandfathered group health plans (including large group and self-insured health plans) and health insurance issuers offering group and individual health insurance coverage (non-QHP issuers), the Departments intend to propose other transparency reporting requirements at a later time, through a separate rulemaking conducted by the Departments, for non-QHP issuers and non-grandfathered group health plans. Those proposed reporting requirements may differ from those prescribed in the HHS proposal under section 1311(e)(3), and will take into account differences in markets, reporting requirements already in existence for non-QHPs (including group health plans), and other relevant factors. The Departments also intend to streamline reporting under multiple reporting provisions and reduce unnecessary duplication. The Departments intend to implement any transparency reporting requirements applicable to non-QHP issuers and non-grandfathered group health plans only after notice and comment, and after giving those issuers and plans sufficient time, following the publication of final rules, to come into compliance with those requirements. *Form Number:* CMS–10572 (OMB control number: 0938–1310); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 160; *Number of Responses:* 160; *Total Annual Hours:* 10,880. (For questions regarding this collection contact Valisha Jackson at (301) 492–5145.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Collection to Support QHP Certification and other Financial Management and Exchange Operations; *Use:* As directed by the rule Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310) (Exchange rule), each Exchange is responsible for the certification and offering of Qualified Health Plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange. A QHP must meet certain minimum certification standards, such as network adequacy, inclusion of Essential Community Providers (ECPs), and non-discrimination. The Exchange is responsible for ensuring that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR 155 and 156, based on the Patient Protection and Affordable Care Act (PPACA), as well as other standards determined by the Exchange. Issuers can offer individual and small group market plans outside of the Exchanges that are not QHPs.

The instruments in this information collection will be used for the 2020 certification process and beyond. Providing these instruments now will give issuers and other stakeholders more opportunity to familiarize themselves with the instruments before releasing the 2020 application. *Form Number:* CMS–10433 (OMB control number: 0938–1187); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments, Private Sector (Business or other for-profits); *Number of Respondents:* 2,892 *Number of Responses:* 2,892; *Total Annual Hours:* 68,666. (For questions regarding this collection contact Joshua Annas at (301) 492–4407).

6. *Type of Information Collection Request:* Request for a new OMB control number; *Title of Information Collection:* The State Flexibility to Stabilize the Market Grant Program Reporting; *Use:* Section 1003 of the Affordable Care Act (ACA) adds a new section 2794 to the PHS Act entitled, ''Ensuring That Consumers Get Value for Their Dollars.'' Specifically, section 2794(a) requires the Secretary of the Department of Health and Human Services (the Secretary) (HHS), in conjunction with the States, to establish a process for the annual review of health insurance premiums to protect consumers from unreasonable rate increases. Section 2794(c) directs the Secretary to carry out a program to award grants to States. Section 2794(c)(2)(B) specifies that any appropriated Rate Review Grant funds that are not fully obligated by the end of FY 2014 shall remain available to the Secretary for grants to States for planning and implementing the insurance market reforms and consumer protections under Part A of title XXVII of the Public Health Service Act (PHS Act). States that are awarded funds under this funding opportunity are required to provide CMS with four quarterly reports and one annual report (except for the last year of the grant) until the end of the grant period detailing the state's progression towards planning and/or implementing the pre-selected market reforms under Part A of Title XXVII of the PHS Act. A final report is due at the end of the grant period. *Form Number:* CMS–10657 (OMB control number: 0938–NEW); *Frequency:* Annually and Quarterly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 31; *Total Annual Responses:* 5; *Total Annual Hours:* 2,108. (For policy questions regarding this collection contact Jim Taing at (301) 492–4182.)

Dated: October 17, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff. Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–23027 Filed 10–22–18; 8:45 am]

BILLING CODE 4120–01–P

[1] PHS Act section 2715A also is incorporated into section 715(a)(1) of the Employee Retirement Income Security Act and section 9815(a)(1) of the Internal Revenue Code.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–E–5940, FDA–2017–E–5941, FDA–2017–E–5943, and FDA–2017–E–5944]

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

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 SILIQ 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 biological 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 December 24, 2018. 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 April 22, 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 December 24, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 24, 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 Nos. FDA–2017–E–5940, FDA–2017–E–5941, FDA–2017–E–5943, and FDA–2017–E–5944 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; SILIQ.'' 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological product will include all the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product SILIQ (brodalumab). SILIQ is indicated for treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies. Subsequent to this approval, the USPTO received patent term restoration applications for SILIQ (U.S. Patent Nos. 7,767,206; 7,939,070; 8,435,518; and 8,545,842) from Kirin-Amgen, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated January 9, 2018, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of SILIQ 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 SILIQ is 3,101 days. Of this time, 2,643 days occurred during the testing phase of the regulatory review period, while 458 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 (21 U.S.C. 355(i)) became effective:* August 22, 2008. The applicant claims September 26, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 22, 2008, which was 30 days after FDA receipt of an earlier IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* November 16, 2015. FDA has verified the applicant's claim that the biologics license application (BLA) for SILIQ (BLA 761032) was initially submitted on November 16, 2015.

3. *The date the application was approved:* February 15, 2017. FDA has verified the applicant's claim that BLA 761032 was approved on February 15, 2017.

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 1,156 days, 906 days, or 847 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: October 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23058 Filed 10–22–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0386]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products.''

DATES: Submit either electronic or written comments on the collection of information by December 24, 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 December 24, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 24, 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–2012–N–0386 for ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products.'' 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