

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

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 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:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or

provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products**

*OMB Control Number 0910–0650—Extension*

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding, among other things, a chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. The Tobacco Control Act created new requirements for the tobacco industry. Section 101 of the Tobacco Control Act amended the FD&C Act by adding sections 905 and 904 (21 U.S.C. 387e and 387d).

Section 905 of the FD&C Act requires the annual registration of any “establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.” Section 905 requires this registration be completed by December 31 of each year.

The Secretary of Health and Human Services (Secretary) has delegated to the Commissioner of Food and Drugs the responsibility for administering the FD&C Act, including section 905. Section 905 of the FD&C Act requires owners or operators of each establishment to register: (1) Their name; (2) places of business; (3) a list of all tobacco products which are manufactured by that person; (4) a copy of all labeling and a reference to the authority for the marketing of any tobacco product subject to a tobacco product standard under section 907 of the FD&C Act (21 U.S.C. 387g) or to premarket review under section 910 of the FD&C Act (21 U.S.C. 387j); (5) a copy of all consumer information and other labeling; (6) a representative sampling of advertisements; (7) upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and (8) upon request made by the Secretary, if the registrant has determined that a tobacco product contained in the product list is not subject to a tobacco product standard established under section 907 of the FD&C Act, a brief statement of the basis upon which the registrant made such determination.

FDA collects the information submitted pursuant to section 905 of the FD&C Act through an electronic portal, and through paper forms (Forms FDA 3741 and FDA 3741a) for those individuals who choose not to use the electronic portal.

FDA has also published a guidance for industry entitled “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments” (<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM191940.pdf>). This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA.

Section 904(a)(1) of the FD&C Act requires that each tobacco product manufacturer or importer submit “a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand” by December 22, 2009. This section applies only to those tobacco products manufactured and distributed before June 22, 2009, and which are still manufactured as of the date of the ingredient listing submission.

Section 904(c) of the FD&C Act requires that a tobacco product

manufacturer: (1) Provide all information required under section 904(a) of the FD&C Act to FDA “at least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment” of the Tobacco Control Act; (2) advise FDA in writing at least 90 days prior to adding any new tobacco additive or increasing in quantity an existing tobacco additive, except for those additives that have been designated by FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use; and (3) advise FDA in writing at least 60 days prior to eliminating or decreasing an existing additive, or adding or increasing an additive that has been designated by FDA through regulation as not a human or animal

carcinogen, or otherwise harmful to health under intended conditions of use.

FDA collects the information submitted pursuant to sections 904(a)(1) and 904(c) of the FD&C Act through an electronic portal, and through a paper form (Form FDA 3742) for those individuals who choose not to use the electronic portal.

In addition to the development of the electronic portal and paper form, FDA published a guidance entitled “Listing of Ingredients in Tobacco Products.” This guidance is intended to assist persons making tobacco product ingredient listing submissions. FDA also provides a technical guide, embedded hints, and a web tutorial to the electronic portal.

The Tobacco Control Act also gave FDA the authority to issue a regulation

deeming all other products that meet the statutory definition of a tobacco product to be subject to Chapter 9 of the FD&C Act (section 901(b) (21 U.S.C. 387a(b)) of the FD&C Act). On May 10, 2016, FDA issued that rule, extending FDA’s tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah, pipe tobacco, nicotine gels, dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976) (“the final deeming rule”).

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

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

FDA form/activity/TCA section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Tobacco Product Establishment Initial Registration and Listing; Form FDA 3741 Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submissions); Sections 905(b), 905(c), 905(d), 905(h), or 905(i).	100	1	100	1.6 .....	160
Tobacco Product Establishment Renewal Registration and Listing; Form FDA 3741 Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper submissions); Sections 905(b), 905(c), 905(d), 905(h), or 905(i).	3,578	1	3,578	.16 (10 minutes) .....	572
Tobacco Product Listing; Form FDA 3742 Listing of Ingredients (Electronic and Paper submissions); Section 904(a)(1).	10	1	10	2 .....	20
Tobacco Product Listing; Form FDA 3742 Listing of Ingredients (Electronic and Paper submissions); Section 904(c).	35	2	70	0.40 (24 minutes) .....	28
Obtaining a Dun and Bradstreet D–U–N–S Number	100	1	100	0.5 (30 minutes) .....	50
Total .....	.....	.....	.....	.....	830

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

The PRA burden estimates have been updated to fully incorporate the use of an electronic system known as FURLS for submitting registration and product listing information to FDA. With the FURLS, manufacturers can enter information quickly and easily. For example, product label pictures can be uploaded directly. We anticipate that most, if not all companies, already have electronic versions of their labels for printing, sales, or marketing purposes.

Product listing information is provided at the time of registration. Currently, registration and listing requirements only apply to domestic establishments engaged in the manufacture, preparation,

compounding, or processing of a tobacco product. This includes importers to the extent that they engage in the manufacture, preparation, compounding, or processing of a tobacco product, including repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package. Foreign establishments are not required to register and list until FDA issues regulations establishing such requirements in accordance with section 905(h) of the FD&C Act. To account for the foregoing, we include both domestic manufacturing establishments and importers in our estimates.

As the deadline for initial establishment registration and product listing for both statutorily regulated and deemed products has passed, FDA estimates that few (up to 100) new establishments will submit one initial establishment registration and product listing report each year. Such new establishments potentially include new vape shop locations that mix or assemble products on the market as of the final deeming rule effective date. The Agency estimates that up to 100 tobacco establishments will each submit 1 initial establishment registration and product listing report each year, which is expected to take 1.6 hours, for a total 160 burden hours.

FDA estimates that the confirmation or updating of establishment registration and product listing information as required by section 905 of the FD&C Act will take 10 minutes annually per confirmation or update per establishment. Based on FDA's experience with current establishment registration and product listings submitted to the Agency, the Agency estimates that on average 3,578 establishments will each submit one confirmation or updated report each year, which is expected to take 0.16 hour (10 minutes) for a total 572 burden hours.

FDA estimates that we have received most tobacco product ingredient submissions for large manufacturers of deemed products. Small manufacturers' deadline for ingredient submissions is November 2018. This is based on the counts we have to date (July 2018), including statutorily regulated products (based on information in our tracking system).

FDA estimates that the submission of ingredient listings required by section 904(a)(1) of the FD&C Act for each establishment will take 2 hours initially. Because this burden estimate covers a timeframe of 3 years, we anticipate almost all section 904(a)(1) tobacco ingredient submissions to have been received before the expiration of the current approval (prior to 11/8/2018 for small manufacturers and large manufacturers, 5/8/18). We are estimating approximately 30 manufacturers may miss their deadline. This is based on estimates of how many large manufacturers we are aware of that have missed their deadline. Because this burden estimate covers 3 years, we are dividing by 3, to yield 10 respondents as a yearly average for this estimate. Therefore, FDA estimates that 10 establishments will initially submit one report annually at 2 hours per report, for a total of 20 hours.

Submissions under 904(c) of the FD&C Act are for any new product that is not yet on the market (e.g., if on the market due to deeming compliance period), newly deemed product manufacturers should have submitted under section 904(a)(1) of the FD&C Act. This includes any statutorily regulated product that would receive a marketing authorization and any new deemed product not subject to the deeming compliance period. For deemed product categories, while we anticipate receiving a large number of premarket applications, there is a portion of these applicants who will have reported their ingredients under section 904(a)(1) as most of these submissions are expected

to be for products subject to the deeming compliance period.

Based on FDA's experience and the actual number of product ingredient listings submitted over the past 3 years, FDA estimates that 35 establishments will each submit two reports (one every 6 months). FDA also estimates that the confirmation or updating of product (ingredient) listing information required by section 904(c) of the FD&C Act is expected to take 0.40 hour (24 minutes) and will take 48 minutes annually for two confirmations or updates per establishment, for a total 28 burden hours. FDA estimates that obtaining a DUNS (data universal numbering system) number will take 30 minutes. FDA assumes that all new establishment facilities that will be required to initially register under section 905 of the FD&C Act would obtain a DUNS number. FDA estimates that up to 100 establishments that would need to obtain this number each year. The total industry burden to obtain a DUNS number is 50 hours.

FDA estimates the total burden for this collection to be 830 hours. We have adjusted our burden estimate, which has resulted in a decrease of 93,086 hours to the currently approved burden. Based on data we reviewed from the past 3 years and projecting the number of remaining establishments that have not registered and submitted product ingredient listings, we revised the number of respondents and burden hours in this information collection.

Dated: October 17, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-23056 Filed 10-22-18; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2017-E-3617, FDA-2017-E-3619, and FDA-2017-E-3618]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; NUPLAZID

**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 NUPLAZID 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 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:

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- 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").