Center's website following the meeting: *https://healthpolicy.duke.edu/events/expanding-access-to-treatment-for-OUD.* Webcast participants will be able to submit questions and comments via the webcast portal. Persons interested in participating in the live webcast must register online by September 19, 2018, by 5 p.m. Eastern Time (see *Registration* section above). Early registration is recommended because webcast connections are limited. Organizations are required to register all participants; however, we request that organizations view the meeting using one connection per location whenever possible.

Other Issues for Consideration: All event materials will be provided to registered attendees via email prior to the meeting and will be made publicly available at the Duke-Margolis Center's website: *https://healthpolicy.duke.edu/events/expanding-access-to-treatment-for-OUD.* A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of the Conference Center.

IV. References

The following references are on display in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 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. Hedegaard, H., M. Warner, and A.M. Miniño, ''Drug Overdose Deaths in the United States, 1999–2016,'' NCHS Data Brief, no. 294, Hyattsville, MD: National Center for Health Statistics. 2017 (available at *https://www.cdc.gov/nchs/products/databriefs/db294.htm*), accessed June 27, 2018.
2. Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, ''Results from the 2016 National Survey on Drug Use and Health: Detailed Tables.'' September 8, 2016 (available at *https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.htm*), accessed June 27, 2018.

Dated: August 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18071 Filed 8–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0449]

Agency Information Collection Activities; Proposed Collection; Comment Request; Sun Protection Factor Labeling and Testing Requirements for Over-the-Counter Sunscreen Drug Products

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 sun protection factor (SPF) labeling and testing requirements for over-the-counter (OTC) sunscreen products containing specified ingredients and marketed without approved applications, and comments on compliance with Drug Facts labeling requirements for all OTC sunscreen products.

DATES: Submit either electronic or written comments on the collection of information by October 22, 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 October 22, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 22, 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–2011–N–0449 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Sun Protection Factor Labeling and Testing Requirements and Drug Facts Labeling for Over-the-Counter Sunscreen Drug 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: 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: 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.

SPF Labeling and Testing Requirements for OTC Sunscreen Products—21 CFR 201.327(a)(1) and (i), 21 CFR 201.66(c) and (d)

OMB Control Number 0910–0717—Extension

I. Background

In the **Federal Register** of June 17, 2011 (76 FR 35620), we published a final rule establishing labeling and effectiveness testing requirements for certain OTC sunscreen products containing specified active ingredients without approved applications (2011 sunscreen final rule; § 201.327 (21 CFR 201.327)). In addition to establishing testing requirements, the 2011 sunscreen final rule lifted the delay of implementing the prior 1999 sunscreen final rule (published in the **Federal Register** of May 21, 1999 (64 FR 27666) and stayed in the **Federal Register** of December 31, 2001 (66 FR 67485) from complying with the 1999 Drug Facts labeling final rule (published in the **Federal Register** of March 17, 1999 (64 FR 13254)), in which we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products in part 201 (21 CFR part 201). Specifically, the 1999 Drug Facts labeling final rule added new § 201.66 to part 201. Section 201.66 establishes content and format requirements for the Drug Facts portion of OTC drug product labels. We specifically exempted OTC sunscreen products from complying with the 1999 Drug Facts labeling final rule until we lifted the stay of the 1999 sunscreen final rule. The 2011 sunscreen final rule became effective December 17, 2012, for sunscreen products with annual sales of $25,000 or more and December 17, 2013, for sunscreen products with annual sales of less than $25,000 when we published an extension date notice in the **Federal Register** of May 11, 2012 (77 FR 27591) (2012 extension date notice).

II. SPF Labeling and Testing for OTC Sunscreens Containing Specified Active Ingredients and Marketed Without Approved Applications

In the **Federal Register** of June 17, 2011 (76 FR 35678), we published a 60-day notice requesting public comment on the proposed collection of information regarding SPF labeling and testing requirements for OTC sunscreen products containing specified ingredients and marketed without approved applications (2011 60-day notice). In that notice, we stated that § 201.327(a)(1) requires the principal display panel (PDP) labeling of a sunscreen covered by the 2011 sunscreen final rule to include the SPF value determined by conducting the SPF test outlined in § 201.327(i). Therefore, that provision resulted in an information collection with a third-party disclosure burden for manufacturers of OTC sunscreens covered by the 2011 sunscreen rule. We determined that products need only complete the testing and labeling required by the 2011 sunscreen rule once and then continue to use the resultant labeling (third-party disclosure) going forward without additional burden. This one-time testing would need to be conducted within the first 3 years after publication of the 2011 sunscreen final rule for all OTC sunscreens covered by that rule.

We determined that the third-party disclosure burden by manufacturers of OTC sunscreens covered by the 2011 sunscreen rule was based on: (1) An estimate of the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information; (2) the conduct of SPF testing based on the estimated number of existing formulations; (3) an estimate of the time to relabel currently marketed OTC sunscreens containing specified ingredients and marketed without approved applications; and (4) testing and labeling of new products introduced each year. The estimate for this burden in the 2011 60-day notice was a total of 30,066 hours in years 1 and 2, and a total of 966 in each subsequent year.

All currently marketed OTC sunscreen drug products are already required to comply with the SPF labeling requirements specified by the 2011 sunscreen final rule. However, our original estimate also included the burden of new products introduced each year. We estimated that as many as

60 new OTC sunscreen products stock keeping units (SKUs) may be introduced each year, which must be tested and labeled with the SPF value determined in the test. We estimated that the 60 new sunscreen SKUs represent 39 new formulations. The burden for testing and labeling these formulations was estimated at 30 hours per year.

We received only two comments on our estimated information collection burden (FDA–2011–N–0449–0002 and FDA–2011–N–0449–0003). These comments were already addressed in FDA's notice entitled ''Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Sun Protection Factor Labeling and Testing Requirements and Drug Facts Labeling for Over-the Counter Sunscreen Drug Products'' published in the **Federal Register** of May 9, 2012 (77 FR 27230).

In the **Federal Register** of April 16, 2015 (80 FR 20499), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Conduct SPF testing in accordance with § 201.327(i) for new sunscreens.	20	1.95	39	24	936
Create PDP labeling in accordance with § 201.327(a)(1) for new sunscreen SKUs.	20	3	60	0.5 (30 minutes)	30
Total					966

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

III. Drug Facts Labeling for OTC Sunscreens

Because the 2011 sunscreen final rule also lifted the delay of implementing the Drug Facts regulations (§ 201.66) for OTC sunscreens, the rule also modified the information collection associated with § 201.66 (currently approved under OMB control number 0910–0340) and added a third-party disclosure burden resulting from requiring OTC sunscreen products to comply with Drug Facts regulations. In the 1999 Drug Facts labeling final rule, we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products, codified in § 201.66. This section establishes requirements for the Drug Facts portion of labels on OTC drug products requiring such labeling, to include uniform headings and subheadings, presented in a standardized order with minimum standards for type size and other graphical features. Therefore, OTC sunscreen products already on the market at that time incurred a one-time burden to comply with the requirements in § 201.66(c) and (d). In the 60-day notice, the burden was estimated as 43,200 hours for existing sunscreen SKUs and 720 hours for new sunscreen SKUs.

The compliance dates for the 2011 sunscreen final rule that lifted the delay of the § 201.66 labeling implementation data for OTC sunscreen products were December 17, 2012, for sunscreen products with annual sales of $25,000 or more and December 17, 2013, for sunscreen products with annual sales of less than $25,000, respectively, when we published the 2012 extension date notice. All currently marketed sunscreen products are, therefore, already required to comply with the Drug Facts labeling requirements in § 201.66 and will incur no further burden in the 1999 Drug Facts labeling final rule. However, new OTC sunscreen drug products will be subject to a one-time burden to comply with Drug Facts labeling requirements in § 201.66. In the 2011 60-day notice, we estimated that as many as 60 new product SKUs marketed each year must comply with Drug Facts regulations. We estimated that these 60 SKUs would be marketed by 30 manufacturers, which will spend approximately 12 hours on each label based on the most recent estimate used for other OTC drug products to comply with the 1999 Drug Facts labeling final rule, including public comments received on this estimate in 2010 that addressed sunscreens. This is equal to 720 hours annually (60 SKUs, 12 hours per SKU). We stated that we do not expect any OTC sunscreens to apply for exemptions or deferrals of the Drug Facts regulations in § 201.66(e). However, we considered this in 2013 and estimated the burden for an exemption or deferral by considering the number of exemptions or deferrals we have received since publication of the 1999 Drug Facts labeling final rule (one response) and estimating that a request for deferral or exemption would require 24 hours to complete. Multiplying the annual frequency of response (0.125) by the number of hours per response (24) gives a total response time for requesting an exemption or deferral equal to 3 hours.

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Format labeling in accordance with § 201.66(c) and (d) for new sunscreen SKUs	20	3	60	12	720
Request for Drug Facts exemption or deferral § 201.66(e)	1	0.125	0.125	24	3
Total					723

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

We note that these estimates may be adjusted in the future development of an upcoming rulemaking on over-the-counter sunscreen products (RIN 0910–AA01). FDA intends to amend this information collection and/or seek approval of additional information collections, as appropriate, concurrent with this rulemaking.

Dated: August 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18073 Filed 8–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–P–1335 and FDA–2018–P–1361]

Determination That DITROPAN XL (Oxybutynin Chloride) Extended Release Tablets, 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Glen Cheng, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6210, Silver Spring, MD 20993–0002, 301–796–1494.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 5 mg, 10 mg, and 15 mg, are the subject of NDA 020897, held by Janssen Pharmaceuticals Inc., and initially approved on December 16, 1998. DITROPAN XL is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, and for the treatment of pediatric patients aged 6 years and older with symptoms of detrusor overactivity associated with a neurological condition (*e.g.,* spina bifida).

In a letter dated December 14, 2017, Janssen Pharmaceuticals Inc. notified FDA that DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 mg, were being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. Although DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 5 mg and 10 mg, were also previously listed in the ''Discontinued Drug Product List'' section of the Orange Book, they are now listed in the ''Prescription Drug Product List'' section of the Orange Book.

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated March 30, 2018 (Docket No. FDA–2018–P–1335), and Ajanta Pharma Limited submitted a citizen petition dated April 2, 2018 (Docket No. FDA–2018–P–1361), under 21 CFR 10.30, requesting that the Agency determine whether DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 5 mg, 10 mg, and 15 mg, were withdrawn from sale for reasons of safety or effectiveness.

As noted, DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 5 mg and 10 mg, are no longer listed in the ''Discontinued Drug Product List'' section of the Orange Book, and therefore we need not determine whether they were withdrawn from sale for reasons of safety or effectiveness.

With regard to DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 mg, after considering the citizen petition and reviewing Agency records, and based on the information we have at this time, FDA has determined under § 314.161 that DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that this drug