

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN<sup>1</sup>

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

<sup>1</sup> 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#### Determination That DITROPAN XL (Oxybutynin Chloride) Extended Release Tablets, 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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or Agency) has determined that DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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

product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DITROPAN XL (oxybutynin chloride) Extended Release Tablets, 15 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 15, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–18045 Filed 8–21–18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–N–2381]

#### The Food and Drug Administration’s Comprehensive, Multi-Year Nutrition Innovation Strategy; Extension of the Comment Period

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

**ACTION:** Notice; extension of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for the notice of a public meeting and request for comments, published in the **Federal Register** of June 27, 2018. The notice announced a public meeting entitled “FDA’s Comprehensive, Multi-Year Nutrition Innovation Strategy” and invited interested parties to provide information on specific topics related to

FDA’s Nutrition Innovation Strategy. We are extending the comment period to give interested parties more time to comment.

**DATES:** FDA is extending the comment period on the notice and its request for comment, published in the **Federal Register** of June 27, 2018 (83 FR 30180). Submit either electronic or written comments by October 11, 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 11, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time, October 11, 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–2381 for “The Food and Drug Administration’s Comprehensive, Multi-Year Nutrition Innovation Strategy; Public Meeting; Request for Comments.” 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.” We will review this copy, including the claimed confidential information, in our 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.