FD&C Act, drugs that must be dispensed with a prescription under section 503(b)(1) of the FD&C Act must bear the ''Rx only'' symbol; if not, they become misbranded. FDA has long interpreted these provisions to mean that section 503(b) of the FD&C Act does not permit the same active ingredient to be simultaneously marketed in both a prescription drug product and a nonprescription drug product unless a meaningful difference exists between the two that makes the prescription product safe only under the supervision of a licensed practitioner.

In this instance, based on studies submitted by the sponsor, FDA determined that the original prescription NIX product no longer met the criteria in section 503(b)(1) of the FD&C Act for prescription use (see 21 CFR 310.200(b)). Therefore, FDA changed NIX's status from prescription to nonprescription. This is commonly referred to as a ''full Rx to OTC switch.'' The permethrin 1% topical creme rinse product (NDA 019918) continued to use the trade name NIX when it switched from prescription to nonprescription. Because FDA concluded that there is no meaningful difference between the currently marketed nonprescription NIX product and its previous prescription version, NIX would be misbranded under section 503(b)(4)(B) of the FD&C Act if it were to bear the symbol ''Rx only.'' Similarly, any generic product referencing prescription NIX (NDA 019435) would also be misbranded under section 503(b)(4)(B) of the FD&C Act, because it would necessarily bear the same labeling as that approved under NDA 019435, including the ''Rx only'' symbol. Moreover, FDA will not approve an ANDA referencing prescription NIX (NDA 019435).

Dated: September 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20520 Filed 9–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1358]

How To Obtain a Covered Product Authorization; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''How To Obtain a Covered Product Authorization.'' This guidance describes how eligible product developers can obtain a Covered Product Authorization (CPA) from FDA under the law widely known as the CREATES Act. The CREATES Act provides a pathway for eligible product developers to obtain access to the product samples they need to fulfill testing and other regulatory requirements to support their applications. As described in further detail below, to make use of this pathway, an eligible product developer seeking to develop a product subject to a Risk Evaluation and Mitigation Strategies (REMS) with elements to assure safe use (ETASU) must obtain a CPA from the Agency. This guidance replaces the December 2014 draft guidance for industry ''How To Obtain a Letter From FDA Stating That Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD,'' which has been withdrawn. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by November 21, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by November 21, 2022.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2022–D–1358 for ''How To Obtain a Covered Product Authorization.'' Received comments 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Rana Carroll, Center for Drug Evaluation and Research, Food and Drug Administration, Building 51, Rm. 6218, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6135.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''How To Obtain a Covered Product Authorization.'' In December 2019, the law widely known as CREATES (referred to herein as ''CREATES'' or ''the CREATES Act'') was enacted as part of the Further Consolidated Appropriations Act of 2020.[1] CREATES makes available a pathway for developers of potential drug and biological products to obtain samples of brand products that they need to support their applications. CREATES establishes a private right of action that allows eligible developers to sue brand companies that refuse to sell them product samples needed to support their applications. If the product developer prevails, the court will order the sale of samples, award attorneys' fees and litigation costs to the product developer, and may impose a monetary penalty on the brand company (21 U.S.C. 355–2(b)(4)).

The product developer must take several specific steps (outlined in the CREATES Act) before the brand company must sell them product samples. One of these steps—if the brand product for which samples are sought is subject to a REMS with ETASU—is that the product developer must first obtain a CPA from FDA (21 U.S.C. 355–2(b)(2)). CREATES does not require this step for products that are not subject to REMS with ETASU. This guidance describes how an eligible product developer can obtain a CPA from FDA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''How To Obtain a Covered Product Authorization.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), 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 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.

Guidance for Industry: How To Obtain a Covered Product Authorization

OMB Control Number 0910–0014—Revision

The revised information collection described in this guidance supports FDA Center for Drug Evaluation and Research's implementation of the law widely known as the CREATES Act, which was enacted as part of the Further Consolidated Appropriations Act of 2020. As described above, the CREATES Act establishes a pathway for eligible product developers to obtain samples of brand products needed to support their applications.

FDA applications referenced in this guidance include abbreviated new drug applications (ANDAs) submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)), new drug applications (NDA) submitted pursuant to section 505(b)(2) of the FD&C Act (21 U.S.C. 355(b)(2)), and applications for biosimilar products submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)).

Product developers typically need brand product samples to, among other things, conduct testing comparing their proposed version of a product to the brand product. For example, an ANDA applicant generally needs to show that its proposed generic drug product is bioequivalent to the brand product (see section 505(j)(2)(A) of the FD&C Act). Bioequivalence is generally demonstrated by conducting studies comparing the proposed generic drug product to the brand product and generic applicants are required to retain samples of the brand product used in testing after a study is complete. Developers of 505(b)(2) and biosimilar

[1] See Public Law 116–94 (Further Consolidated Appropriations Act, 2020, enacting Division N, Title I, Subtitle F, Section 610—Actions for Delays of Generic Drugs and Biosimilar Biological Products (Dec. 20, 2019)). The provisions of this law related to access to product samples were codified at 21 U.S.C. 355–2 and 355–1(l).

products must also typically conduct comparative testing requiring access to brand product samples.

Under the CREATES Act, the product developer must take several specific steps (outlined in the CREATES Act) before the brand company is required to sell them product samples. If the brand product for which samples are sought is subject to a REMS with ETASU, the product developer must first obtain a CPA from FDA (21 U.S.C. 355–2(b)(2)). (CPAs are only available for products that are subject to a REMS with ETASU. To prevail in the private right of action established by CREATES, an eligible product developer seeking samples of a product that is *not* subject to a REMS with ETASU does not need to obtain a CPA.)

This information collection enables eligible product developers to obtain CPAs from FDA so that they can utilize the pathway made available by the CREATES Act. An ANDA, 505(b)(2), or biosimilar product developer's use of the CREATES pathway is voluntary, as is the product developer's request for a CPA. Accordingly, under this information collection, FDA will collect information voluntarily provided by eligible product developers in the form of requests for CPAs and supporting documentation. Requests for CPAs for samples of brand products used for purposes of development and testing that involve human clinical trials should be accompanied by study protocols, informed consent documents, and informational materials for testing demonstrating that safety protections comparable to those in the REMS for the brand product will be provided for in the study(ies) for which the samples are sought.

For generic drug products, a request for a CPA is submitted through the CDER NextGen collaboration Portal as complex controlled correspondence to an ANDA. For 505(b)(2) applications and biosimilar applications, the request for a CPA is submitted to the pre-investigational new drug application (pIND) or investigational new drug application (IND) file, and a copy is sent to any existing marketing application for the product and to *ONDCommunications@fda.hhs.gov.*

Respondents for this information collection are drug and biological product developers that are seeking to use the CREATES pathway to obtain samples of brand products needed to support their applications.

For ANDA, 505(b)(2), and biosimilar products, the burden of requesting a CPA is being added to OMB Control No. 0910–0014.

Based on prior experience, FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance Section IV.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
CPA Requests for NDA/Biologics License Application products	1	1	1	5	5
CPA Requests for ANDA products	11	2	22	5	110
Total					115

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

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20523 Filed 9–21–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0872]

Electronic Submission Template for Medical Device 510(k) Submissions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Electronic Submission Template for Medical Device 510(k) Submissions.'' This final guidance is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process. This guidance document provides further standards for the submission of 510(k)s by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements.

DATES: The announcement of the guidance is published in the **Federal Register** on September 22, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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