Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On April 19, 2000, FDA approved ANDA 075328 for pemoline tablets, 18.75 mg, 37.5 mg, and 75 mg, for the conditions of use in the labeling of new drug application (NDA) 016832, the reference listed drug on which it relied. On October 24, 2005, the Agency issued a Postmarket Drug Safety Information for Patients and Providers communication entitled ''Information for Healthcare Professionals: Pemoline Tablets and Chewable Tablets (Marketed as CYLERT)'' which concluded the overall liver toxicity risk of CYLERT (pemoline) (NDAs 016832 and 017703) and generic pemoline products outweighed the benefits of these products (*https://wayback.archive-it.org/7993/20171114124349/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126461.htm*).

All holders of approved applications for pemoline products, including Vintage, ceased marketing the products at that time. On June 21, 2012, Vintage requested that FDA withdraw approval of ANDA 075328, pursuant to § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing. Vintage stated in its June 21, 2012, request for withdrawal of approval of ANDA 075328 that it had discontinued manufacturing the product since April 2005.

In the **Federal Register** issue of July 19, 2013 (78 FR 43210), FDA erroneously included ANDA 075328 in a list of drug applications for which approval was being withdrawn under § 314.150(c). In a separate notice published in this issue of the **Federal Register**, FDA corrected the July 19, 2013, notice to remove ANDA 075328 from the list of applications whose approval was withdrawn under § 314.150(c).

For the reasons discussed above, and in accordance with the applicant's request, approval of ANDA 075328 for pemoline tablets, 18.75 mg, 37.5 mg, and 75 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of pemoline tablets, 18.75 mg, 37.5 mg, and 75 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: May 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–11991 Filed 6–5–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0861]

Cover Letter Attachments for Controlled Correspondence and Abbreviated New Drug Application Submissions; Guidance for Industry; 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 for industry entitled ''Cover Letter Attachments for Controlled Correspondence and ANDA Submissions.'' This guidance is intended to assist prospective applicants, applicants, and holders of abbreviated new drug applications (ANDAs) with optional attachments that can be used when preparing cover letters that accompany controlled correspondence, original ANDAs, amendments to ANDAs, and supplements to approved ANDAs submitted to FDA. This guidance finalizes the draft guidance of the same title issued on December 13, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on June 6, 2023.

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 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–2021–D–0861 for ''Cover Letter Attachments for Controlled Correspondence and ANDA Submissions.'' 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 this 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 electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jonathan Hughes, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Rm. 1668, Silver Spring, MD 20993–0002, 240–702–3970, *Jonathan.Hughes@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Cover Letter Attachments for Controlled Correspondence and ANDA Submissions.'' This guidance is intended to assist prospective applicants, applicants, and holders of ANDAs with optional attachments that can be used when preparing cover letters that accompany controlled correspondence, original ANDAs, amendments to ANDAs, and supplements to approved ANDAs submitted to FDA.

A cover letter is generally included with controlled correspondence to the Office of Generic Drugs and submissions to an ANDA file. While a cover letter is not required content for an ANDA, the cover letter is a part of the electronic common technical document hierarchy and is included in Module 1 of an ANDA submission.

The cover letter provides an overview of the submission and helps FDA ensure that the submission is properly triaged and assigned to the appropriate assessors. In an effort to ensure that submissions are effectively managed by FDA and acted upon within the performance review goal dates reflected in the Generic Drug User Fee Amendments (GDUFA) Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027 commitment letter (GDUFA III Commitment Letter),[1] FDA has developed cover letter attachments to accompany, not replace, applicants' cover letters for common submissions, including controlled correspondence, original ANDAs, and amendments to ANDAs, as well as supplements to approved ANDAs. These cover letter attachments have been designed as a checklist to reflect common types of information applicants are expected to address in their cover letters. The attachments are intended both to serve as a useful guide to help applicants prepare their cover letters and to assist FDA in the triage and management of submissions.

This guidance finalizes the draft guidance entitled ''Cover Letter Attachments for Controlled Correspondence and ANDA Submissions'' issued on December 13, 2021 (86 FR 70849). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarifying that use of the cover letter attachments are voluntary; defining several terms that may have been ambiguous (*e.g.,* ''administrative general correspondence'' and ''approved citizen petitions''); and adding updated information on labeling carve-outs and requests for reconsideration. In addition, editorial changes were made to improve clarity, such as adding lines to denote where information should be filled in by the applicant and minor reformatting of the attachments in the appendices.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Cover Letter Attachments for Controlled Correspondence and ANDA Submissions.'' 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.

[1] Available at: *https://www.fda.gov/media/153631/download.*

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 (including subpart C) for to the content and format of ANDAs, including original ANDAs, amendments to ANDAs, and supplements to approved ANDAs, submitted by applicants and approved by FDA have been approved under OMB control number 0910–0001. The collections of information for Form FDA 356h (NDA and ANDA cover letter) have been approved under OMB control number 0910–0338.

Applicants submit to FDA controlled correspondence along with cover letters related to generic drug development and FDA approval. The collections of information for such submissions have been approved under OMB control number 0910–0797. The collections of information in 21 CFR part 11 for electronic records and electronic signatures have been approved under OMB control number 0910–0303. The collections of information in 21 CFR part 211 about the manufacture of the drug have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the final 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: May 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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