guidances-drugs or *https://www.regulations.gov.*

Dated: December 6, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26923 Filed 12–10–21; 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Cover Letter Attachments for Controlled Correspondences and Abbreviated New Drug Application Submissions; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Cover Letter Attachments for Controlled Correspondences and Abbreviated New Drug Application Submissions.''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 to the Office of Generic Drugs (OGD), as well as original ANDAs, amendments to ANDAs, and supplements to approved ANDAs submitted to FDA.

DATES: Submit either electronic or written comments on the draft guidance by February 11, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

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–2021–D–0861 for ''Cover Letter Attachments for Controlled Correspondences 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 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 electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Nicole Park, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Rm. 1725, Silver Spring, MD 20993–0002, 240–402–7764, *Nicole.Park@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Cover Letter Attachments for Controlled Correspondences 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 to OGD, as well as original ANDAs, amendments to ANDAs, and supplements to approved ANDAs submitted to FDA.

A cover letter is generally included with controlled correspondence to OGD 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 (eCTD) 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 set by the Generic Drug User Fee Amendments, 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 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 ''Cover Letter Attachments for Controlled Correspondences 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.

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. 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 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: December 6, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26893 Filed 12–10–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1301]

Q3C(R8) Impurities: Guidance for Residual Solvents; International Council for Harmonisation; 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 ''Q3C(R8) Impurities: Guidance for Residual Solvents.'' The guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. This guidance provides recommendations for permitted daily exposures (PDEs) for three additional residual solvents: 2-Methyltetrahydrofuran, cyclopentyl methyl ether, and tert-butyl alcohol. The PDEs were developed according to the methods for establishing exposure limits included in the guidance for industry ''Q3C: Impurities Residual Solvents'' (Q3C guidance). The Q3C PDE levels are added and revised as new toxicological data for solvents become available. This guidance finalizes the draft guidance entitled ''Q3C(R8) Recommendations for the Permitted Daily Exposures for Three Solvents—2-Methyltetrahydrofuran, Cyclopentyl Methyl Ether, and Tert-Butyl Alcohol—According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents'' issued on May 27, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on December 13, 2021.

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–2020–D–1301 for ''Q3C(R8) Impurities: Guidance for Residual Solvents.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at