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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Cover Letter Attachments for Controlled Correspondences and ANDA Submissions.''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]

BILLING CODE 4164–01–P

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

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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Timothy McGovern, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 22, Rm. 6426, Silver Spring, MD 20993–0002, 240–402–0477; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Q3C(R8) Impurities: Guideline for Residual Solvents.'' The guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner. By harmonizing the regulatory requirements in regions around the world, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, standardized marketing application submissions, and made many other improvements in the quality of global drug development and manufacturing and the products available to patients.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. Additionally, the Membership of ICH has expanded to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by involving technical experts from both regulators and industry parties in detailed technical harmonization work and the application of a science-based approach to harmonization through a consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of May 27, 2020 (85 FR 31785), FDA published a notice announcing the availability of a 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.'' The notice gave interested persons an opportunity to submit comments. In the **Federal Register** of June 5, 2020 (85 FR 34638), FDA issued a correction providing that the date by which to submit comments was July 27, 2020.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in April 2021.

First published in December 1997, the Q3C guidance provides recommendations on the use of less toxic solvents in the manufacture of drug substances and dosage forms and sets pharmaceutical limits for residual solvents (organic volatile chemicals) in drug products. Q3C PDE levels are added and revised as new toxicological data for solvents become available. As part of the maintenance process, the Q3C(R8) guidance provides final PDEs for three additional residual solvents: 2-methyltetrahydrofuran, cyclopentyl methyl ether, and tert-butyl alcohol. Additional information regarding supporting studies was incorporated into the guidance based on comments received, but the recommended PDEs for the three new residual solvents are identical to those published in the draft guidance issued on May 27, 2020. This

guidance finalizes the guidance issued on May 27, 2020.

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 ''Q3C(R8) Impurities: Guidance for Residual Solvents.'' 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 58 have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: December 6, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26889 Filed 12–10–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1287]

Actavis LLC, et al.; Withdrawal of Approval of Six Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of six abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 12, 2022.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 202603	Methoxsalen Capsules, 10 milligrams (mg)	Actavis LLC, (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Bldg. A, Parsippany, NJ 07054.
ANDA 205274	Amoxicillin Tablets, 125 mg and 250 mg	Hikma Pharmaceuticals LLC, 1809 Wilson Rd., Columbus, OH 43228.
ANDA 205513	Carisoprodol Tablets, 250 mg and 350 mg	Strides Pharma Global Pte. Limited, U.S. Agent, Strides Pharma Inc., 2 Tower Center Blvd., Suite 1102, East Brunswick, NJ 08816.
ANDA 206410	Itraconazole Capsules, 100 mg	Do.
ANDA 207536	Flucytosine Capsules, 250 mg and 500 mg	Do.
ANDA 208227	Dutasteride Capsules, 0.5 mg	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of January 12, 2022. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on January 12, 2022, may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: December 7, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26892 Filed 12–10–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Single-Source Supplement for Title X Services in Texas

AGENCY: Office of Population Affairs, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Office of Population Affairs (OPA) announces the award of a single-source supplement to provide Title X family planning services in Texas to Women's Health and Family Planning Association of Texas (d.b.a. Every Body Texas). The supplement will enable Every Body Texas to expand provision of emergency contraception and other family planning services to clients across the state of Texas to address the anticipated increased demand for family planning services following passage of TX SB8.

DATES: December 13, 2021.

FOR FURTHER INFORMATION CONTACT: Jessica Swafford Marcella, Deputy Assistant Secretary for Population