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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 12, 2022.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