

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://](https://www.regulations.gov)

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 12, 2022.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

Affairs, Office of Population Affairs, Office of the Assistant Secretary for Health, Department of Health and Human Services at Jessica.marcella@hhs.gov and 240-453-2800.

SUPPLEMENTARY INFORMATION:

Recipient: Every Body Texas, Austin, TX.

Purpose of the Award: The purpose of this award is to address the anticipated need for family planning services across the state of Texas in response to TX SB8. With this funding, Every Body Texas will expand the provision of emergency contraception and other family planning services to clients across the state of Texas through their existing Title X network.

Amount of Award: \$750,000.

Project Period: The project period for the supplemental award will not exceed the recipient's current project period, which is scheduled to end on March 31, 2022.

OPA currently provides \$15,820,000 in Title X funding to Every Body Texas. With their Title X funding, Every Body Texas provides Title X family planning services across Texas through a network of 36 subrecipients and 192 service sites. In 2019, Every Body Texas provided family planning services to 176,697 clients across the State of Texas.

Supplemental funding will enable Every Body Texas to expand provision of emergency contraception and other family planning services to clients across the state of Texas through their existing Title X network, in response to TX SB8. Title X family planning services are services that assist in preventing or achieving pregnancy. Title X clinics must provide a broad range of acceptable and effective family planning methods and services, including: Contraceptive education, counseling, and methods (includes hormonal methods; fertility awareness-based methods; barrier methods; abstinence; and/or permanent sterilization); services centered around pre-conception health and achieving pregnancy (includes infertility services; STI prevention, education, screening, and treatment; HIV testing and referral); and pregnancy diagnosis and counseling. The broad range of family planning services does not include abortion as a method of family planning.

This award is being made non-competitively because Every Body Texas is the only existing Title X grantee providing services across the entire state of Texas. Issuing a single-source supplemental award to Every Body Texas would expand services across the entire state.

Dated: November 30, 2021.

Jessica Swafford Marcella,

Deputy Assistant Secretary for Population Affairs, Office of Population Affairs, Office of the Assistant Secretary for Health.

[FR Doc. 2021-26850 Filed 12-10-21; 8:45 am]

BILLING CODE 4150-30-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Proposed Information Collection: Addendum to Declaration for Federal Employment, Child Care and Indian Child Care Worker Positions (OMB No. 0917-0028)

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments; request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on the information collection titled, "Addendum to Declaration for Federal Employment, Child Care and Indian Child Care Worker Positions," Office of Management and Budget (OMB) Control Number 0917-0028. A copy of the supporting statement is available at www.regulations.gov (see Docket ID: IHS_FRDOC_0001).

DATES: February 11, 2022. Your comments regarding this information collection are best assured of having full effect if received within 60 days of the date of this publication.

For Comments: Submit comments to Sharon Duran by one of the following methods:

- *Email:* Sharon.Duran@ihs.gov.

Comments submitted in response to this notice will be made available to the public by publishing them in the 30-day **Federal Register** notice for this information collection. For this reason, please do not include information of a confidential nature, such as sensitive personal information or proprietary information. If comments are submitted via email, the email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Evonne Bennett, Information Collection Clearance Officer at: Evonne.Bennett@ihs.gov or 301-443-4750.

SUPPLEMENTARY INFORMATION: This previously approved information collection project was last published in the **Federal Register** on November 27, 2018, and allowed 30 days for public comment. No public comment was received in response to the notice. This notice announces our intent to submit this collection, which expires February 28, 2022, to OMB for approval of an extension, and to solicit comments on specific aspects for the proposed information collection.

Title: Addendum to Declaration for Federal Employment, Child Care and Indian Child Care Worker Positions (OMB No. 0917-0028). *Type of Information Collection Request:* Extension, without revision, of currently approved information collection, 0917-0028, Addendum to Declaration for Federal Employment, Child Care and Indian Child Care Worker Positions. There are no program changes or adjustments in burden hours. *Form(s):* Addendum to Declaration for Federal Employment, Child Care and Indian Child Care Worker Positions. *Need and Use of Information Collection:* This is a request for approval of the collection of information as required by section 408 of the Indian Child Protection and Family Violence Prevention Act, Public Law 101-630 [104 stat. 4544, 25 U.S.C. 3201-3210]; 34 U.S.C. 20351; and 42 CFR part 136, subpart K.

The IHS is required to compile a list of all authorized positions within the IHS where the duties and responsibilities involve regular contact with, or control over, Indian children; and to conduct an investigation of the character of each individual who is employed, or is being considered for employment, in a position having regular contact with, or control over, Indian children. 25 U.S.C. 3207(a)(1) and (2). Section 3207(a)(3) of Title 25 requires regulations prescribing the minimum standards of character for individuals appointed to positions involving regular contact with, or control over, Indian children, and section 3207(b) provides that such standards shall ensure that no such individuals have been found guilty of, or entered a plea of nolo contendere or guilty to, any felonious offense, or any two or more misdemeanor offenses, under Federal, State, or Tribal law involving crimes of violence; sexual assault, molestation, exploitation,