information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Use Review (DUR) Program; *Use:* States must provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid patient. This review includes screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Pharmacists must make a reasonable effort to obtain, record, and maintain Medicaid patient profiles. These profiles must reflect at least the patient's name, address, telephone number, date of birth/age, gender, history, *e.g.,* allergies, drug reactions, list of medications, and pharmacist's comments relevant to the individual's drug therapy.

The States must conduct RetroDUR which provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, inappropriate or medically unnecessary care. Patterns or trends of drug therapy problems are identified and reviewed to determine the need for intervention activity with pharmacists and/or physicians. States may conduct interventions via telephone, correspondence, or face-to-face contact.

Annual reports are submitted to CMS for the purposes of monitoring compliance and evaluating the progress of States' DUR programs. The information submitted by States is reviewed and results are compiled by CMS in a format intended to provide information, comparisons, and trends related to States' experiences with DUR. States benefit from the information and may enhance their programs each year based on State reported innovative practices that are compiled by CMS from the DUR annual reports. *Form Number:* CMS–R–153 (OMB control number: 0938–0659); *Frequency:* Yearly, quarterly, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 663; *Total Annual Hours:* 41,004. (For policy questions regarding this collection contact Mike Forman at 410–786–2666.)

Dated: September 11, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–19967 Filed 9–13–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0113]

Facta Farmaceutici S.p.A., et al.; Withdrawal of Approval of 23 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 5, 2019. The document announced the withdrawal of approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants, effective March 7, 2019. The document erroneously included ANDA 077895 for Ursodiol Capsules USP, 300 milligrams, held by Impax Laboratories, LLC. This notice corrects that error.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993, 301–348–3035.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of Tuesday, February 5, 2019 (84 FR 1745), in FR Doc. 2019–01129, the following correction is made:

1. On page 1746, in the table, the entry for ANDA 077895 is removed.

In a separate notice published in this issue of the **Federal Register**, FDA is withdrawing the approval of ANDA 077895 under 21 CFR 314.150(d).

Dated: September 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19920 Filed 9–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–3347]

Medical Devices; Exemption From Premarket Notification: Class II; Powered Wheeled Stretcher; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it has received a petition requesting exemption from the premarket notification requirements for powered wheeled stretchers. These devices are battery-powered tables with wheels that are intended for medical purposes for use by patients who are unable to propel themselves independently and who must maintain a prone or supine position for prolonged periods because of skin ulcers or contractures (muscle contractions). FDA is publishing this notice to obtain comments in accordance with procedures established by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments by November 15, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 15, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 15, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2019–P–3347 for ''Medical Devices; Exemption From Premarket Notification: Powered Wheeled Stretcher.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

• 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Bryan Benesch, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1538, Silver Spring, MD 20993–0002, 301–796–5506.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

FDA classifies devices into one of three regulatory classes: class I, class II, or class III, based on the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness (see section 513 of the FD&C Act (21 U.S.C. 360c)). Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations, 21 CFR part 807 subpart E, require persons who intend to market a new device to submit and obtain clearance of a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Pub. L. 114–255) (Cures Act) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(2) of the FD&C Act provides that, 1 calendar day after the date of publication of the final list under paragraph (1)(B), FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act upon its own initiative or a petition of an interested person, if FDA determines that a report under section 510(k) is not necessary to assure the safety and effectiveness of the device. To do so, FDA must publish in the **Federal Register** notice of its intent to exempt the device, or the petition, and provide a 60-calendar day period for public comment. Within 120 days after the issuance of this notice, FDA must publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' (Class II 510(k) Exemption Guidance) (available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf*). As discussed in that guidance document, FDA generally considers the following factors to determine whether a report under section 510(k) is necessary for class II devices: (1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA may also consider that, even when exempting devices, these devices would

still be subject to the general limitations on exemptions.

III. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Stryker, 3800 East Centre Ave., Portage, MI 49002, for powered wheeled stretcher, classified under 21 CFR 890.3690. With this notice FDA is seeking comments on the petition in accordance with section 510(m)(2) of the FD&C Act.

IV. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120.

Dated: September 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19978 Filed 9–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3839]

Impax Laboratories, LLC; Withdrawal of Approval of an Abbreviated New Drug Application for Ursodiol Capsules USP, 300 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing the approval of abbreviated new drug application (ANDA) 077895 for Ursodiol Capsules USP, 300 milligrams (mg), held by Impax Laboratories, LLC (Impax). Impax requested withdrawal of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of September 16, 2019.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 301–348–3035.

SUPPLEMENTARY INFORMATION: On July 27, 2006, FDA approved ANDA 077895 for Ursodiol Capsules USP, 300 mg, submitted by CorePharma, LLC (CorePharma). According to annual reports filed with the Agency, this product has not been commercially manufactured since February 2010.

In a letter dated August 9, 2011, FDA informed CorePharma that it had concerns about the validity of bioequivalence data submitted with ANDA 077895 from studies conducted by a certain contract research organization intended to establish bioequivalence of CorePharma's product to its reference listed drug (RLD), new drug application 019594, Actigall (Ursodiol) Capsules, 300 mg. In that letter, FDA directed CorePharma to supplement its ANDA with either: (1) New bioequivalence studies or (2) re-assays of the samples from the original bioequivalence studies. In a letter dated January 26, 2012, CorePharma submitted a request for an extension of time to submit new bioequivalence data in response to the Agency's August 9, 2011, letter. On February 10, 2012, the Agency granted CorePharma's request for an extension to submit new bioequivalence data by October 30, 2012.

FDA subsequently sent another letter to CorePharma on August 19, 2016, requesting that CorePharma provide the requested bioequivalence data within 30 calendar days or voluntarily seek withdrawal of ANDA 077895 under § 314.150(d) (21 CFR 314.150(d)). In response to the August 19, 2016, correspondence, FDA received a letter from CorePharma dated September 7, 2016, stating that CorePharma did not wish to request the withdrawal of approval of ANDA 077895 for Ursodiol Capsules. In February 2017, the Agency was notified that the ownership of ANDA 077895 was transferred from CorePharma to Impax.

On April 24, 2017, FDA issued a letter to Impax, noting that as of the date of the April 24, 2017, letter, FDA had not received the requested bioequivalence data. In the April 24, 2017, correspondence, FDA strongly suggested to Impax that it voluntarily seek withdrawal of ANDA 077895 under § 314.150(d) as a result of failing to provide data and information establishing bioequivalence to the RLD. In a letter dated February 25, 2019, Impax informed FDA that it would like to request the withdrawal of ANDA 077895 under § 314.150(d). Additionally, in a March 14, 2019, correspondence to FDA, Impax waived any opportunity for hearing provided under § 314.150(a).

In the **Federal Register** of February 5, 2019 (84 FR 1745), FDA erroneously included ANDA 077895 in a list of drug applications for which approval was being withdrawn under § 314.150(c). Elsewhere in this issue of the **Federal Register** FDA is publishing a correction to that notice to remove ANDA 077895 from the list of applications whose approval was withdrawn under § 314.150(c). In addition, for the reasons discussed above, and because of Impax's request, FDA is withdrawing approval of ANDA 077895, and all amendments and supplements thereto, under § 314.150(d). Distribution of Ursodiol Capsules USP, 300 mg, in 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: September 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19908 Filed 9–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3277]

Revocation of Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection and/or Diagnosis of Zika Virus

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Siemens Healthcare Diagnostics, Inc. (Siemens), for the ADVIA Centaur Zika test. FDA revoked this Authorization on July 17, 2019, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), in consideration of the premarket notification submission submitted to FDA by Siemens for the ADVIA Centaur Zika test that was determined to be substantially equivalent to a legally marketed class II predicate device on July 17, 2019. The revocation, which includes an explanation of the reasons for revocation, is reprinted in this document.