Application No.	Drug	Applicant
NDA 019292	MD–76R (diatrizoate meglumine and diatrizoate sodium) Injection, 66%/10%.	Liebel-Flarsheim Co. LLC.
NDA 020014	Maxair Autohaler (pirbuterol acetate inhalation aerosol), EQ 0.2 mg base/inhalation.	Bausch Health US, LLC.
NDA 021041	DepoCyt (cytarabine liposome) Injection, 10 mg/mL	Pacira Pharmaceuticals, Inc., 5 Sylvan Way, Suite 300, Parsippany, NJ 07054.
NDA 021338	Ionsys (fentanyl iontophoresis transdermal system), 40 mcg/activation.	The Medicines Co., 8 Sylvan Way, Parsippany, NJ 07054.
NDA 021575	Fosamax (alendronate sodium) Oral Solution, EQ 70 mg base/75 mL.	Merck Sharp & Dohme Corp., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889–0100.
NDA 022222	Ultresa (pancrelipase (amylase, lipase, protease)), Delayed-Release Capsules, 8,000 USP Units/4,000 USP Units/8,000 USP Units and 27,600 USP Units/13,800 USP Units/27,600 USP Units, and 41,400 USP Units/20,700 USP Units/41,400 USP Units, and 46,000 USP Units/23,000 USP Units/46,000 USP Units.	Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940.
NDA 022396	Dyloject (diclofenac sodium) Injection, 37.5 mg/mL	Javelin Pharmaceuticals, Inc., a subsidiary of Hospira Inc., 275 North Field Dr., Dept. 0392, Bldg. H1–3S, Lake Forest, IL 60045.
NDA 203568	Kynamro (mipomersen sodium) Injection, 200 mg/mL	Kastle Therapeutics, 181 West Madison St., Suite 300, Chicago, IL 60602.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of August 2, 2019. Approval of each entire application is withdrawn, including any strengths or products inadvertently missing from the table.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 August 2, 2019 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: June 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14219 Filed 7–2–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–1366]

Determination That CLAFORAN (Cefotaxime Sodium) for Injection, 500 Milligrams/Vial, 1 Gram/Vial, 2 Grams/Vial and 10 Grams/Vial, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that CLAFORAN (cefotaxime sodium) for injection, 500 milligrams (mg)/vial, 1 gram (g)/vial, 2 g/vial and 10 g/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Beth Holck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993–0002, 240–402–7133.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CLAFORAN (cefotaxime sodium) for injection, 500 mg/vial, 1 g/vial, 2 g/vial and 10 g/vial, is the subject of NDA 050547, held by US Pharmaceutical Holdings II LLC, and initially approved on March 11, 1981. CLAFORAN is indicated for the treatment of patients with serious bacterial infections in eight different organ systems caused by susceptible strains of microorganisms, as specified in the labeling.

In a letter dated February 9, 2018, US Pharmaceutical Holdings II LLC notified FDA that CLAFORAN (cefotaxime for injection) 500 mg/vial, 1 g/vial, 2 g/vial and 10 g/vial was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Cardinal Health Regulatory Sciences submitted a citizen petition dated January 31, 2019 (Docket No. FDA–2019–P–1366), under 21 CFR 10.30, requesting that the Agency determine whether CLAFORAN (cefotaxime sodium) for injection, 500 mg/vial, 1 g/vial, 2 g/vial and 10 g/vial, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CLAFORAN (cefotaxime sodium) for injection, 500 mg/vial, 1 g/vial, 2 g/vial and 10 g/vial was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that CLAFORAN (cefotaxime sodium) for injection, 500 mg/vial, 1 g/vial, 2 g/vial and 10 g/vial was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CLAFORAN (cefotaxime sodium) for injection, 500 mg/vial, 1 g/vial, 2 g/vial and 10 g/vial from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CLAFORAN (cefotaxime sodium) for injection, 500 mg/vial, 1 g/vial, 2 g/vial and 10 g/vial, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: June 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14172 Filed 7–2–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3208]

DHL Laboratories Inc.; Withdrawal of Approval of a New Drug Application for Dextrose 5% Injection in Plastic Container, 5 Grams/100 Milliliters

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of new drug application (NDA) 019971 for Dextrose 5% Injection in Plastic Container, 5 grams (g)/100 milliliters (mL), held by DHL Laboratories Inc., 155 Medical Science Dr., Union, SC 23979. The basis for the withdrawal is that the holder of the NDA has repeatedly failed to file required annual reports for the NDA.

DATES: Approval is withdrawn as of July 3, 2019.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holder of an approved application to market a new drug for human use is required to submit annual reports to FDA concerning its approved application in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of August 29, 2018 (83 FR 44056), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of NDA 019971 because DHL Laboratories Inc. had failed to submit required annual reports for the NDA. DHL Laboratories Inc. did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by the holder of the NDA not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the NDA and a waiver of any contentions concerning the legal status of the drug product. FDA is withdrawing approval of NDA 019971 for Dextrose 5% Injection in Plastic Container, 5 g/100 mL.

FDA finds that DHL Laboratories Inc. has repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, FDA finds DHL Laboratories Inc. has waived any contentions concerning the legal status of the drug product. Therefore, under these findings, approval of NDA 019971, and all amendments and supplements thereto, is hereby withdrawn as of July 3, 2019.

Dated: June 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14137 Filed 7–2–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1114]

Pharmaceutical Distribution Supply Chain Pilot Projects; Reopening of Comment Period; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period; request for information.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notices (requests for information) that published in the **Federal Register** of April 15, 2016, and April 28, 2017. FDA is requesting comments regarding issues related to utilizing the product identifier for product tracing, improving the technical capabilities of the supply chain, and identifying system attributes that are necessary to implement the requirements established under the Drug Supply Chain Security Act (DSCSA). The information gathered from reopening of the comment period will allow supply chain stakeholders to share information about relevant piloting activities that are conducted outside of FDA's DSCSA Pilot Project Program to inform DSCSA implementation by FDA and supply chain stakeholders.

DATES: FDA is reopening the comment period on the notices (requests for information) published April 15, 2016 (81 FR 22279), and April 28, 2017 (82 FR 19737). Submit either electronic or written comments by June 28, 2022.

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 June 28, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 28, 2022. Comments received by mail/hand delivery/courier