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Agency determine whether CLAFORAN (cefotaxime sodium) for injection, 500 mg/vial, 1 g/vial, 2 g/vial and 10 g/vial, was withdrawn from sale for reasons of safety or effectiveness.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under § 314.161 that CLAFORAN (cefotaxime sodium) for injection, 500 mg/vial, 1 g/vial, 2 g/vial and 10 g/vial was not withdrawn for reasons of safety or effectiveness.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suggesting that CLAFORAN (cefotaxime sodium) for injection, 500 mg/vial, 1 g/vial, 2 g/vial and 10 g/vial was withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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

(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–2016–N–1114 for ''Pharmaceutical Distribution Supply Chain Pilot Projects; Reopening of Comment Period; Request for Information.'' 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: Daniel Bellingham, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *DSCSAPilotProjects@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA is interested in comments regarding past or present pilot projects related to enhancing the safety and security of the pharmaceutical distribution supply chain; this may include information related to piloting activities that are conducted outside of FDA's DSCSA Pilot Project Program. Stakeholders that may be interested in responding to this request for information include manufacturers, repackagers, wholesale distributors, dispensers, State and Federal authorities, solution providers, standards organizations, and other interested persons. FDA is particularly interested in learning about the practices, processes, and systems that supply chain stakeholders have used or considered using in such pilot projects. This includes, but is not limited to, information about the following:

- Utilizing the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference;
- Technical capabilities of each supply chain sector to develop and implement the systems and processes needed to utilize the product identifier to enhance the tracing of a product; or
- System attributes that are necessary to implement the requirements established under the DSCSA.

Interested persons are requested to provide any other relevant information that may inform FDA's implementation of the requirements for enhanced product tracing and verification under the DSCSA.

FDA is reopening the comment period for the requests for information for 3 years, until June 28, 2022. The Agency believes that a 3-year comment period allows adequate time for interested persons to submit new, additional, or updated comments on these important issues as they work to implement requirements under the DSCSA.

Dated: June 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–14147 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–0692]

Determination That THAM Solution (Tromethamine) Injectable, 3.6 Grams/100 Milliliters, 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 THAM Solution (tromethamine) injectable, 3.6 grams (g)/100 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new