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DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 Therefore, under these findings, approval of NDA 019971, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Dated: June 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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