4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-2391]

Miles Laboratories Inc.; Withdrawal of Approval of an Abbreviated New Drug Application for Alcohol and Dextrose Injection; 5 Milliliters/100 Milliliters, 5 Grams/100 Milliliters

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of an abbreviated new drug application (ANDA) for Alcohol and Dextrose Injection, 5 milliliters (mL)/100 mL, 5 grams (g)/100 mL. The bases for the withdrawal are that the ANDA holder has repeatedly failed to file required annual reports for this ANDA and that the Agency has scientific data and experience to show that the drug product under this ANDA is unsafe for use under the conditions of use for which the product was approved.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kaetochi Okemgbo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6224, Silver Spring, MD 20993-0002, 301-796-1546, Kaetochi.Okemgbo@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holder of an approved ANDA to market a new drug for human use is required to submit annual reports to FDA concerning its approved ANDA under §§ 314.81 and 314.98 (21 CFR 314.81 and 314.98). Additionally, under 21 CFR 314.161, FDA previously determined that Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL, approved under ANDA 083483 was withdrawn from sale for safety and effectiveness reasons (see 86 FR 72606, December 22, 2021) (this determination also applied to other applications and to the 10 mL/100 mL, 5 g/100 mL strength of Alcohol and Dextrose Injection approved under

new drug application (NDA) 004589). As explained in our *Federal Register* notice determining that Alcohol and Dextrose was withdrawn from sale for safety and effectiveness reasons, Alcohol and Dextrose Injection is indicated to provide increased caloric intake. The use of Alcohol and Dextrose raises several safety concerns because there are many risks associated with the exposure to alcohol. Alcohol is contraindicated for use in patients with neurologic disorders, such as seizures, who have current or past substance abuse problems, or who are pregnant. It can cause intoxication, respiratory depression, and disturbances in serum glucose levels. FDA-approved alternatives for intravenous calorie supplementation that do not include alcohol were approved after these Alcohol and Dextrose products and are available today.

In the *Federal Register* of October 24, 2022 (87 FR 64227), FDA published a notice of opportunity for a hearing (NOOH) on a proposal to withdraw approval of ANDA 083483, held by Miles Laboratories Inc., the last holder of record, under § 314.150(b)(1) (21 CFR 314.150(b)(1)) because the ANDA holder has repeatedly failed to submit the required annual reports and under § 314.150(a)(2)(i) because the Agency has scientific data and experience to show that the drug product approved under ANDA 083483, Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL, is unsafe for use under the conditions of use for which the product was approved. The ANDA holder 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 a waiver of the opportunity for a hearing by the ANDA holder concerning the proposal to withdraw approval of the ANDA and a waiver of any contentions concerning the legal status of the drug product. Accordingly, FDA is withdrawing approval of ANDA 083483.

Therefore, for reasons discussed above, FDA finds that: (1) the ANDA holder has failed to submit reports required under §§ 314.81 and 314.98 and section 505(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(k)) and (2) the Agency has scientific data and experience to show that the drug product approved under ANDA 083483, Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL, is unsafe for use under the conditions of use for

which the product was approved. In addition, under § 314.200, FDA finds that the ANDA holder has waived its opportunity for a hearing and any contentions concerning the legal status of the drug products. Therefore, based on these findings and pursuant to the authority under section 505(e) of the FD&C Act, approval of ANDA 083483 and all amendments and supplements thereto is hereby withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Dated: February 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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