accomplished; and (3) treatment of postmenopausal osteoporosis in women greater than 5 years postmenopause.

MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Maiva Pharma Private Ltd. submitted a citizen petition dated October 12, 2022 (Docket No. FDA–2022–P–2517), under 21 CFR 10.30, requesting that the Agency determine whether MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, was voluntarily withdrawn for reasons other than safety or efficacy.

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this time, FDA has determined under § 314.161 that MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, 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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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 MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, 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. ANDAs that refer to MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, may 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: February 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03389 Filed 2–16–23; 8:45 am]

BILLING CODE 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 February 17, 2023.

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 February 17, 2023.

Dated: February 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03367 Filed 2–16–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–2842]

Determination That Dihydroergotamine Mesylate 45 Injection USP, 1 Milligram/Milliliter, 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 D.H.E. 45 (dihydroergotamine mesylate) injection USP, 1 milligram (mg)/milliliter (mL), 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: Donna Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3600, *Donna.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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.

D.H.E. 45 (dihydroergotamine mesylate) injection USP, 1 mg/mL, is the subject of NDA 005929, held by Bausch Health US, LLC, and initially approved on April 12, 1946. D.H.E. 45 (dihydroergotamine mesylate) is indicated for the acute treatment of migraine headaches with or without aura and the acute treatment of cluster headache episodes.

In a letter dated June 13, 2022, Bausch Health US, LLC notified FDA that D.H.E. 45 (dihydroergotamine mesylate) injection USP, 1 mg/mL, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Baxter Healthcare Corporation submitted a citizen petition dated November 11, 2022 (Docket No. FDA–2022–P–2842), under 21 CFR 10.30, requesting that the Agency determine whether D.H.E. 45 (dihydroergotamine mesylate) injection USP, 1 mg/mL, 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 D.H.E. 45 (dihydroergotamine mesylate) injection USP, 1 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that D.H.E. 45 (dihydroergotamine mesylate) injection USP, 1 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of D.H.E. 45 (dihydroergotamine mesylate) injection USP, 1 mg/mL, 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 D.H.E. 45 (dihydroergotamine mesylate) injection USP, 1 mg/mL, 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: February 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03381 Filed 2–16–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0438]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; ADB-BUTINACA; Alpha-PiHP; 3-Methylmethcathinone; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing interested persons with the opportunity to submit written comments concerning recommendations by the World Health Organization (WHO) to impose international manufacturing and distributing restrictions, under international treaties, on certain drug substances. The comments received in response to this notice will be considered in preparing the United States' position on these proposals for a meeting of the United Nations