enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

**SUPPLEMENTARY INFORMATION:** *Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss postmarketing requirement 3033–11, issued to application holders of new drug applications (NDAs) for extended-release and long-acting opioid analgesics to evaluate long-term efficacy of opioid analgesics and the risk of opioid-induced hyperalgesia. The discussion will focus on a clinical trial designed to address these objectives.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before April 6, 2023, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 28, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 29, 2023.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Rhea Bhatt (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 13, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–03370 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–2517]**

### Determination That MIACALCIN (Calcitonin Salmon) Injection, 100 USP Units/Milliliter (mL), 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, Agency, or we) has determined that MIACALCIN (calcitonin salmon) injection, 100 USP Units/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for calcitonin salmon injection, 100 USP Units/mL, if all other legal and regulatory requirements are met.

**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.

MIACALCIN (calcitonin salmon) injection, 100 USP Units/mL, is the subject of NDA 017808, held by Mylan Ireland Ltd., and initially approved on July 3, 1986. MIACALCIN is indicated for: (1) the treatment of symptomatic Paget's disease of bone in patients with moderate to severe disease characterized by polyostotic involvement with elevated serum alkaline phosphatase and urinary hydroxyproline excretion; (2) early treatment of hypercalcemic emergencies, along with other appropriate agents, when a rapid decrease in serum calcium is required, until more specific treatment of the underlying disease can be

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.