learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On April 15, 2021, the committee will discuss biologics license application (BLA) 125734 for donislecel (purified allogeneic deceased donor pancreas derived islets of Langerhans). The applicant, CellTrans, Inc., has requested an indication for the ''treatment of brittle Type 1 diabetes mellitus (T1D).'' The morning session will discuss issues related to the characterization and critical quality attributes of donislecel as they relate to product comparability in the context of consistent product quality and clinical effectiveness. The afternoon session will discuss results from the clinical trials included in BLA 125734.

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 submitted to the Docket (see **ADDRESSES**) on or before April 8, 2021, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:45 p.m. and 2:45 p.m. 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 31, 2021. 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 April 1, 2021.

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 Jarrod Collier at *ctgtac@fda.hhs.gov* (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/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings* 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 10, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03173 Filed 2–16–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–P–1511 and FDA–2020–P–1549]

Determination That NYMALIZE (nimodipine), Oral Solution, 3 Milligrams/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, the Agency, or we) has determined that NYMALIZE (nimodipine), oral solution, 3 milligrams (mg)/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 nimodipine, oral solution, 3 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Ayako Sato, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 240–402–4191, *Ayako.sato@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)(7)), which 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.'' 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; section 505(j)(7) of the FD&C Act).

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 (§ 314.161 (21 CFR 314.161)). 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. FDA may not approve an ANDA that does not refer to a listed drug (see section 505(j)(4) of the FD&C Act).

NYMALIZE (nimodipine), oral solution, 3 mg/mL, is the subject of NDA 203340, held by Arbor Pharmaceuticals, LLC (Arbor), and initially approved on May 10, 2013. NYMALIZE is indicated for the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage from ruptured intracranial berry aneurysms regardless of their post-ictus

neurological condition (*i.e.,* Hunt and Hess Grades I through V).

In a letter dated May 4, 2020, Arbor notified FDA that NYMALIZE (nimodipine), oral solution, 3 mg/mL was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. As indicated in the Orange Book, Arbor markets a 6 mg/mL strength of NYMALIZE (nimodipine) oral solution, which was approved through NDA 203340/S–011 on April 8, 2020.

Annora Pharma Private Limited submitted a citizen petition dated June 6, 2020 (Docket No. FDA–2020–P–1511) and Windels Marx Lane & Mittendorf, LLC submitted a citizen petition dated June 10, 2020 (Docket No. FDA–2020–P–1549), both under 21 CFR 10.30, requesting that the Agency determine whether NYMALIZE (nimodipine), oral solution, 3 mg/mL was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and comments submitted to the dockets and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that NYMALIZE (nimodipine), oral solution, 3 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NYMALIZE (nimodipine), oral solution, 3 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NYMALIZE (nimodipine), oral solution, 3 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events.

A comment submitted by Arbor suggests that it was necessary to discontinue marketing the 3 mg/mL strength to mitigate potential confusion between the 3 mg/mL and 6 mg/mL strengths of NYMALIZE (nimodipine), oral solution. FDA disagrees. While discontinuation of the 3 mg/mL strength is one way to reduce the risk of confusion between the two strengths, there are other (often-used) mitigation strategies that may be employed to reduce the risk of confusion among multiple marketed strengths of a drug that could have been used by Arbor. Arbor's comment also states that FDA should find that the 3 mg/mL strength was discontinued for safety reasons because the Agency made similar determinations for BREVIBLOC (esmolol hydrochloride) injection, 250 mg/mL, 10-mL ampule, and the original formulation of PROTONIX I.V. (pantoprazole sodium) for injection. Our finding that the 3 mg/mL strength for NYMALIZE was not withdrawn from sale for reasons of safety is factually distinguishable from BREVIBLOC and PROTONIX I.V.

Based on a thorough evaluation of the information we have available to us and the latest version of the approved labeling for NYMALIZE (nimodipine), oral solution, 3 mg/mL, we have determined that this drug product would be considered safe and effective if it were reintroduced to the market today. Certain labeling changes should be considered to prevent future medication errors due to the presence of two different strengths of NYMALIZE (nimodipine), oral solution, on the market (*i.e.,* NYMALIZE (nimodipine), oral solution, 3 mg/mL and NYMALIZE (nimodipine), oral solution, 6 mg/mL), but no existing safety signals or efficacy concerns make labeling changes necessary.

Accordingly, the Agency will continue to list NYMALIZE (nimodipine), oral solution, 3 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. ANDAs that refer to NYMALIZE (nimodipine), oral solution, 3 mg/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 10, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03083 Filed 2–16–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Surgical Sciences, Biomedical Imaging and Bioengineering.

Date: March 16, 2021.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yuanna Cheng, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7814, Bethesda, MD 20892, (301) 435–1195, *Chengy5@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR20–117: Maximizing Investigators' Research Award (MIRA) for Early Stage Investigators (R35—Clinical Trial Optional).

Date: March 17–18, 2021.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Guoqin Yu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1276, *guoqin.yu@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Immune Responses and Vaccines to Microbial Infections.

Date: March 17–18, 2021.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barna Dey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, Bethesda, MD 20892, 301–451–2796, *bdey@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Healthcare Delivery and Methodologies.

Date: March 17, 2021.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karen Nieves Lugo, MPH, Ph.D., Scientific Review Officer, Center for