DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0923]

Determination That ANTIZOL (Fomepizole) Injection, 1.5 Grams/1.5 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA or Agency) has determined that ANTIZOL (fomepizole) Injection, 1.5 grams (g)/1.5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness.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 the ANDAs meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Kaetochi Okemgbo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6272, Silver Spring, MD 20993–0002, 240–825–9944, *Kaetochi.Okemgbo@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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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.

ANTIZOL (fomepizole) Injection, 1.5 g/1.5 mL, is the subject of NDA 020696, held by Par Pharmaceuticals Inc., and initially approved on December 4, 1997. ANTIZOL is indicated as an antidote for ethylene glycol (such as antifreeze) or methanol poisoning, or for use in suspected ethylene glycol or methanol ingestion, either alone or in combination with hemodialysis. ANTIZOL (fomepizole) Injection, 1.5 g/1.5 mL is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Gland Pharma Ltd. submitted a citizen petition dated August 19, 2021 (Docket No. FDA–2021–P–0923), under 21 CFR 10.30, requesting that the Agency determine whether ANTIZOL (fomepizole) Injection, 1.5 g/1.5 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 ANTIZOL (fomepizole) Injection, 1.5 g/1.5 mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ANTIZOL (fomepizole) Injection, 1.5 g/1.5 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ANTIZOL (fomepizole) Injection, 1.5 g/1.5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ANTIZOL (fomepizole) Injection, 1.5 g/1.5 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: December 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27699 Filed 12–21–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

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

The meeting 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 cooperative agreement applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; CTSA.

Date: January 26–27, 2022.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Victor Henriquez, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892, (301) 435–0813, *henriquv@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology,

Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: December 16, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–27691 Filed 12–21–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

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

The meeting 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: National Institute of Environmental Health Sciences Special Emphasis Panel; Mechanism for Time-Sensitive Research Opportunities in Environmental Health Sciences (R21).

Date: January 10, 2022.

Time: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Durham, NC 27709 (Virtual Meeting).

Contact Person: Laura A. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709, 984–287–3328, *laura.thomas@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: December 16, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–27690 Filed 12–21–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods Communities of Practice Webinar on New Approach Methodologies To Assess (Developmental) Neurotoxicity; Notice of Public Webinar; Registration Information

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announces a public webinar ''New Approach Methodologies to Assess (Developmental) Neurotoxicity.'' The webinar is organized on behalf of ICCVAM by the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). Interested persons may participate via the web meeting platform. Time will be allotted for questions from the audience. Information about the webinar and registration are available at *https://ntp.niehs.nih.gov/go/commprac-2022.*

DATES:

Webinar: January 25, 2022, 10:00 a.m. to approximately 11:30 a.m. EST.

Registration for Webinar: January 4, 2022, until 11:30 a.m. EST January 25, 2022.

Registration to view the webinar is required.

ADDRESSES: Webinar web page: *https://ntp.niehs.nih.gov/go/commprac-2022.*

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Kleinstreuer, Acting Director, NICEATM, email: *nicole.kleinstreuer@nih.gov,* telephone: (984) 287–3150.

SUPPLEMENTARY INFORMATION:

Background: ICCVAM promotes the development and validation of toxicity testing methods that protect human health and the environment while replacing, reducing, or refining animal use. ICCVAM also provides guidance to test method developers and facilitates collaborations that promote the development of new test methods. To address these goals, ICCVAM will hold a Communities of Practice webinar on ''New Approach Methodologies to Assess (Developmental) Neurotoxicity.''

The nervous system has unique characteristics and can have different sensitivity to toxic substances compared to other organ systems. Effects of chemicals on the nervous system can be affected by concurrent exposures to other substances. During early life stages, exposure to neuroactive drugs and environmental toxins can interact and/or interfere with developmental processes of the brain, which can in turn result in structural and/or functional alterations. Traditional (developmental) neurotoxicity tests use mammals, but the high cost and low throughput of these tests make them impractical to use for all chemicals of potential concern. In addition, it is challenging to correlate the interpretation of animal data to complex human neurological effects. Therefore, interest is increasing in exploring human cell-based assays, computational systems, and other alternatives to traditional animal tests that can be used to predict chemical effects on the developing and adult nervous system.

''New approach methodologies'' (NAMs) refers to any non-animal technology or approach, or combination of these, that can be used to provide information on chemical hazard and risk assessment. This webinar will discuss NAMs that are being considered or developed for assessing potential effects of chemicals on the nervous system. Key insights and ongoing activities will be described in two presentations featuring speakers from U.S. federal research and regulatory agencies. The preliminary agenda and additional information about presentations will be posted at *https://ntp.niehs.nih.gov/go/commprac-2022* as available.

Webinar and Registration: This webinar is open to the public with time scheduled for questions by participants following each presentation. Registration for the webinar is required and will be open from January 4, 2022, through 11:30 a.m. EST on January 25, 2022. Registration is available at *https://ntp.niehs.nih.gov/go/commprac-2022.* Interested individuals are encouraged to visit this web page to stay abreast of the most current webinar information. Registrants will receive instructions on how to access and participate in the webinar in the email confirming their registration.

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency committee composed of representatives from 17 federal regulatory and research agencies that require, use, generate, or disseminate