it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for submission of investigational new drug applications, 21 CFR part 312, have been approved under 0910–0014. The collections of information for submission of new drug applications, 21 CFR part 314, have been approved under 0910–0001. The collections of information for submission of biologic license applications, 21 CFR part 601, have been approved under 0910–0338. The collections of information for submission of premarket approval applications, 21 CFR part 807, subpart E; investigational device exemptions, 21 CFR part 812; premarket notifications, 21 CFR part 814, subparts A through E; humanitarian device exemptions, 21 CFR part 814, subpart H; and De Novo classification requests, 21 CFR part 860, subpart D, have been approved under OMB control numbers 0910–0120, 0910–0078, 0910–0231, 0910–0332, and 0910–0844, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: February 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02962 Filed 2–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–1104]

Determination That ARISTOSPAN (Triamcinolone Hexacetonide) Injectable Suspension, 20 Milligrams/Milliliter and 5 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 or Agency) has determined that ARISTOSPAN (triamcinolone hexacetonide) injectable suspension, 20 milligrams (mg)/milliliter (mL) and 5 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness.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 triamcinolone hexacetonide injectable suspension, 20 mg/mL and 5 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Diana Pomeranz, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6288, Silver Spring, MD 20993–0002, 240–402–4654, *Diana.Pomeranz@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 FDA's approval of 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.

ARISTOSPAN (triamcinolone hexacetonide) injectable suspension, 20 mg/mL and 5 mg/mL, is the subject of NDA 016466, held by Sandoz, Inc., and initially approved on July 29, 1969. ARISTOSPAN 20 mg/mL is indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, acute and subacute bursitis, acute nonspecific tenosynovitis, epicondylitis, rheumatoid arthritis, and synovitis of osteoarthritis. ARISTOSPAN 5 mg/mL is indicated for alopecia areata; discoid lupus erythematosus; keloids; localized hypertrophic, infiltrated, inflammatory lesions of granuloma annulare, lichen planus, lichen simplex chronicus (neurodermatitis), and psoriatic plaques; necrobiosis lipoidica diabeticorum; and cystic tumors of an aponeurosis or tendon (ganglia).

ARISTOSPAN (triamcinolone hexacetonide) injectable suspension, 20 mg/mL and 5 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Medexus Pharma, Inc., submitted a citizen petition dated June 9, 2022 (Docket No. FDA–2022–P–1104), under 21 CFR 10.30, requesting that the Agency determine whether ARISTOSPAN (triamcinolone hexacetonide) injectable suspension, 20 mg/mL, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 5 mg/mL strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

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 ARISTOSPAN (triamcinolone hexacetonide) injectable

suspension, 20 mg/mL and 5 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ARISTOSPAN (triamcinolone hexacetonide) injectable suspension, 20 mg/mL and 5 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ARISTOSPAN (triamcinolone hexacetonide) injectable suspension, 20 mg/mL and 5 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 ARISTOSPAN (triamcinolone hexacetonide) injectable suspension, 20 mg/mL and 5 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 ARISTOSPAN (triamcinolone hexacetonide) injectable suspension, 20 mg/mL and 5 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 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02984 Filed 2–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; High Risk Multi-Center Clinical Study Implementation and Planning Grant in the Area of Achalasia

Date: April 3, 2023.

Time: 12:45 p.m. to 2:45 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maria E. Davila-Bloom, Ph.D., Scientific Review Officer, NIDDK/Scientific Review Branch, National Institutes of Health, 6707 Democracy Blvd., Room 7013, Bethesda, MD 20892, 301–402–6711, *davila-bloomm@extra.niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 7, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–02978 Filed 2–10–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Chronic Dysfunction and Integrative Neurodegeneration Study Section, February 15, 2023, 08 a.m. to February 16, 2023, 07 p.m., Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015 which was published in the **Federal Register** on January 24, 2023, 88 FR 4193, Doc 2023–01308.

This meeting is being amended to change the location from Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015 to Canopy by Hilton, 940 Rose Avenue, North Bethesda, MD 20852. The meeting is closed to the public.

Dated: February 7, 2023.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–02982 Filed 2–10–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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, contract proposals and repayment program discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, contract proposals and repayment program, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Member Special Emphasis Panel; Conflict: Developmental Biology.

Date: March 2, 2023.

Time: 9:00 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2125D, Bethesda, MD 20892 (Virtual Assistant Meeting).

Contact Person: Jagpreet Singh Nanda, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2125D, Bethesda, MD 20892, (301) 451–4454, *jagpreet.nanda@nih.gov*.

Name of Committee: National Institute of Child Health and Human Development Function, Integration, and Rehabilitation Sciences Members'' Special Emphasis Panel; Conflict.

Date: March 3, 2023.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892 (Virtual Assistant Meeting).