

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0412]

Determination That FOLVITE (Folic Acid), Oral Tablets, 1 Milligram, and Other Drug Products, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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 these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, Stacy.Kane@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 generally known as the “Orange Book.” Under FDA regulations, a drug is 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of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

| Application No. | Drug name | Active ingredient(s) | Strength(s) | Dosage form/route | Applicant |
|-----------------|--|---|---|--------------------------------|------------------------|
| NDA 005897 | FOLVITE | Folic Acid | 1 Milligram (mg) | Tablet; Oral | Wyeth Ayerst Pharms. |
| NDA 005897 | FOLVITE | Folic Acid | 5 mg/Milliliter (mL) | Injectable; Injection | Wyeth Ayerst Pharms. |
| NDA 014691 | ALKERAN | Melphalan | 2 mg | Tablet; Oral | Apotex Inc. |
| NDA 015923 | HALDOL | Haloperidol Lactate | Equivalent to (EQ) 5 mg Base/mL | Injectable; Injection | Janssen Pharms. |
| NDA 016042 | DYAZIDE | Hydrochlorothiazide; Triamterene | 25 mg; 50 mg, 25 mg; 37.5 mg | Capsule; Oral | GlaxoSmithKline. |
| NDA 017959 | ADRUCIL | Fluorouracil | 50 mg/mL | Injectable; Injection | Pharmacia & Upjohn Co. |
| NDA 017993 | HYDERGINE | Ergoloid Mesylates | 0.5 mg, 1 mg | Tablet; Oral | Novartis AG. |
| NDA 018082 | DEPAKENE | Valproic Acid | 250 mg/5 mL | Syrup; Oral | AbbVie Inc. |
| NDA 018116 | CYCLOCORT | Amcinonide | 0.025%, 0.1% | Cream; Topical | Astellas. |
| NDA 018498 | CYCLOCORT | Amcinonide | 0.1% | Ointment; Topical | Astellas. |
| NDA 018985 | ORTHO-NOVUM 7/7/7 | Ethinyl Estradiol; Norethindrone | 0.035 mg; 0.5 mg, 0.035 mg; 0.75 mg, 0.035 mg; 1 mg | Tablet; Oral | Janssen Pharms. |
| NDA 019297 | NOVANTRONE | Mitoxantrone Hydrochloride | EQ 20 mg Base/10 mL, EQ 2 mg Base/mL | Injectable; Injection | EMD Serono Inc. |
| NDA 019927 | NIZORAL | Ketoconazole | 2% | Shampoo; Topical | Janssen Pharms. |
| NDA 020207 | ALKERAN | Melphalan Hydrochloride | EQ 50 mg Base/Vial | Injectable; Injection | Apotex Inc. |
| NDA 020262 | TAXOL | Paclitaxel | 6 mg/mL | Injectable; Injection | HQ Specialty Pharma. |
| NDA 020281 | ULTRAM | Tramadol Hydrochloride | 100 mg | Tablet; Oral | Janssen Pharms. |
| NDA 021692 | ULTRAM ER | Tramadol Hydrochloride | 100 mg, 200 mg, 300 mg | Tablet, Extended Release; Oral | Valeant Pharms. |
| NDA 021844 | DESONATE | Desonide | 0.05% | Gel; Topical | Leo Pharma. |
| NDA 022008 | REQUIP XL | Ropinirole Hydrochloride | EQ 2 mg Base, EQ 4 mg Base, EQ 6 mg Base, EQ 8 mg Base, EQ 12 mg Base | Tablet, Extended Release; Oral | GlaxoSmithKline LLC. |
| NDA 050639 | CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER. | Ciindamycin Phosphate | EQ 6 mg Base/mL, EQ 12 mg Base/mL, EQ 18 mg Base/mL | Injectable; Injection | Pfizer. |
| NDA 050684 | ZOSYN | Piperacillin Sodium; Tazobactam Sodium. | EQ 2 g Base/Vial; EQ 250 mg Base/Vial, EQ 3 g Base/Vial; EQ 375 mg Base/Vial, EQ 4 g Base/Vial; EQ 500 mg Base/Vial, EQ 36 g Base/Vial; EQ 4.5 g Base/Vial. | Injectable; Injection | Wyeth Ayerst Pharms. |
| ANDA 062336 | MUTAMYCIN | Mitomycin | 40 mg/Vial | Injectable; Injection | Bristol-Myers Squibb. |

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08940 Filed 4–26–22; 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: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neuroscience of Basic Visual Processes Study Section.

Date: June 8–9, 2022.

Time: 10:00 a.m. to 4:00 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: Kirk Thompson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301–435–1242, kgt@mail.nih.gov.

Name of Committee: Vascular and Hematology Integrated Review Group; Basic Biology of Blood, Heart and Vasculature Study Section.

Date: June 16–17, 2022.

Time: 9:00 a.m. to 9:00 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: Katherine M. Malinda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, (301) 435–0912, malindakm@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 22, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–08958 Filed 4–26–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical 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: NIGMS Initial Review Group; Training and Workforce Development Study Section–D; Review of IMSD and PREP Applications.

Date: June 16–17, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of General Medical Science, Natcher Bldg. 45, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Tracy Koretsky, Ph.D., Scientific Review Officer, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, MSC 6200, Room 3An.12F, Bethesda, MD 20892, 301 594 2886, tracy.koretsky@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 22, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–08968 Filed 4–26–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

The meeting will be open to the public via online meeting. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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: Fogarty International Center Advisory Board.

Date: June 6–7, 2022.

Closed: June 6, 2022, 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate the second level of grant applications.

Place: Fogarty International Center, National Institutes of Health, 31 Center Drive, Room B2C02, Bethesda, MD 20892 (Virtual Meeting).

Open: June 7, 2022, 12:00 p.m. to 3:00 p.m.