Dated: October 19, 2017.

G. Matthew Warren,

Director, Office of Scientific Integrity.

[FR Doc. 2017–23019 Filed 10–23–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5715]

Watson Laboratories, Inc., and Barr Laboratories, Inc., Subsidiaries of Teva Pharmaceuticals USA, Inc.; Withdrawal of Approval of 54 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 54 abbreviated new drug applications (ANDAs) from two applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of November 24, 2017.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1

Application No.	Drug	Applicant
ANDA 061717	Doxycycline Hyclate Capsules USP, Equivalent to (EQ) 50 milligrams (mg) base and EQ 100 mg base.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 062087	Erythromycin Estolate Capsules USP, EQ 250 mg base	Do.
ANDA 062318	Gentamicin Injection USP, EQ 10 mg base/milliliter (mL) and EQ 40 mg base/mL.	Do.
ANDA 062816	Ampicillin for Injection USP, EQ 125 mg base/vial, EQ 250 mg base/vial, EQ 500 mg base/vial, EQ 1 gram (g) base/vial, and EQ 2 g base/vial.	Do.
ANDA 062994	Ampicillin for Injection USP, EQ 10 g base/vial	Do.
ANDA 062999	Erythromycin Delayed-Release Tablets USP, 500 mg	Barr Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 064036	Cefuroxime for Injection USP, EQ 7.5 g base/vial	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 070296	Diazepam Injection USP, 5 mg/mL	Do.
ANDA 070412	Furosemide Tablets USP, 20 mg	Do.
ANDA 070435	Ibuprofen Tablets USP, 200 mg	Do.
ANDA 070436	Ibuprofen Tablets USP, 400 mg	Do.
ANDA 070437	Ibuprofen Tablets USP, 600 mg	Do.
ANDA 070449	Furosemide Tablets USP, 20 mg	Do.
ANDA 070450	Furosemide Tablets USP, 40 mg	Do.
ANDA 070515	Tolazamide Tablets USP, 500 mg	Do.
ANDA 070528	Furosemide Tablets USP, 80 mg	Do.
ANDA 071238	Doxepin Hydrochloride (HCl) Capsules USP, EQ 50 mg base	Do.
ANDA 071547	Ibuprofen Tablets USP, 800 mg	Do.
ANDA 072397	Diazepam Injection USP, 5 mg/mL	Do.
ANDA 072407	Fenoprofen Calcium Tablets USP, EQ 600 mg base	Do.
ANDA 072602	Fenoprofen Calcium Tablets USP, EQ 600 mg base	Do.
ANDA 072630	Albuterol Tablets USP, EQ 4 mg base	Do.
ANDA 072825	Baclofen Tablets USP, 20 mg	Do.
ANDA 073013	Metaproterenol Sulfate Tablets USP, 10 mg	Do.
ANDA 073445	Meperidine HCl Injection USP, 100 mg/mL	Do.
ANDA 074025	Guanabenz Acetate Tablets USP, EQ 4 mg base and EQ 8 mg base	Do.
ANDA 074114	Dobutamine Injection USP, EQ 12.5 mg base/mL	Do.
ANDA 074163	Naproxen Tablets USP, 250 mg, 375 mg, and 500 mg	Do.
ANDA 074287	Piroxicam Capsules USP, 10 mg and 20 mg	Do.
ANDA 074303	Pentamidine Isethionate for Injection, 300 mg/vial	Do.
ANDA 074437	Pindolol Tablets USP, 5 mg and 10 mg	Do.
ANDA 074456	Alprazolam Tablets USP, 0.25 mg, 0.5 mg, and 1 mg	Do.
ANDA 077643	Topiramate Tablets USP, 25 mg, 50 mg, 100 mg, and 200 mg	Do.
ANDA 080728	Diphenhydramine HCl Capsules USP, 25 mg	Do.
ANDA 080968	Dexamethasone Tablets USP, 0.75 mg	Do.
ANDA 081040	Chlorzoxazone Tablets USP, 500 mg	Do.
ANDA 081149	Hydroxyzine HCl Tablets USP, 10 mg	Do.
ANDA 081189	Hydrochlorothiazide Tablets USP, 25 mg	Do.
ANDA 081216	Estropipate Tablets USP, 6 mg	Do.
ANDA 083232	Hydrochlorothiazide Tablets USP, 50 mg	Do.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 085720	Meprobamate Tablets USP, 200 mg	Do.
ANDA 085721	Meprobamate Tablets USP, 400 mg	Do.
ANDA 085778	Hydroxyzine HCl Injection USP, 25 mg/mL	Do.
ANDA 086096	Chlorpheniramine Maleate Injection USP, 10 mg/mL	Do.
ANDA 086189	Ergoloid Mesylates Sublingual Tablets USP, 0.5 mg	Do.
ANDA 086598	Nandrolone Decanoate Injection USP, 100 mg/mL	Do.
ANDA 086795	Chlorothiazide Tablets USP, 250 mg	Do.
ANDA 087183	Ergoloid Mesylates Sublingual Tablets USP, 1 mg	Do.
ANDA 087296	Chlorthalidone Tablets USP, 25 mg	Do.
ANDA 087521	Chlorthalidone Tablets USP, 50 mg	Do.
ANDA 087772	Prednisone Tablets USP, 50 mg	Do.
ANDA 087979	Chloroquine Phosphate Tablets USP, EQ 150 mg base	Do.
ANDA 088030	Chloroquine Phosphate Tablets USP, EQ 300 mg base	Do.
ANDA 089042	Procainamide HCl Extended-Release Tablets USP, 750 mg	Do.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of November 24, 2017. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: October 18, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–23046 Filed 10–23–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44).

Date: November 17, 2017.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Vasundhara Varthakavi, Ph.D., DVM, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3E70, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5020, *varthakaviv@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 18, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–22967 Filed 10–23–17; 8:45 am]

BILLING CODE 4140–01–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; International Research Ethics Training.

Date: November 16, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Karin F. Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, (301) 254–9975, *helmersk@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR16–121 Early-Stage Preclinical Validation of Therapeutic Leads for Diseases of Interest to the NIDDK (R01).

Date: November 16, 2017.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Raul Rojas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, Bethesda, MD 20892, (301) 451–6319, *rojasr@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Macromolecular Structure and Function.

Date: November 20, 2017.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: C-L Albert Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of