

Application No.	Drug	Applicant
ANDA 074945 .....	Atracurium Besylate Injection, 10 mg/milliliter (mL) .....	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 077251 .....	Finasteride Tablets USP, 5 mg .....	Gedeon Richter Plc., c/o Gedeon Richter USA, Inc., 119 Cherry Hill Rd., Suite 325, Parsippany, NJ 07054.
ANDA 077983 .....	Gemcitabine for Injection USP, Equivalent to (EQ) 200 mg base/vial and EQ 1 g/vial.	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 080425 .....	Texacort (hydrocortisone) Topical Solution, 1% .....	Mission Pharmacal Co., 10999 IH 10 West, Suite 1000, San Antonio, TX 78230.
ANDA 083242 .....	Amen (medroxyprogesterone acetate) Tablets, 10 mg ..	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 085455 .....	Dexamethasone Tablets USP, 0.25 mg .....	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc..
ANDA 086308 .....	Homapin-10 (homatropine methylbromide) Tablets USP, 10 mg.	Mission Pharmacal Co.
ANDA 086309 .....	Homapin-5 (homatropine methylbromide) Tablets USP, 5 mg.	Do.
ANDA 086310 .....	Equipin (homatropine methylbromide) Chewable Tablets, 3 mg.	Do.
ANDA 086711 .....	Beta-2 (isoetharine hydrochloride (HCl)) Inhalation Solution, 1%.	Nephron Pharmaceuticals, Corp., 4500 12th St. Extension, West Columbia, SC 20172.
ANDA 087438 .....	Folicet (folic acid) Tablets USP, 1 mg .....	Mission Pharmacal Co.
ANDA 087939 .....	Trimethobenzamide HCl Injection, 100 mg/mL .....	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of September 12, 2018. 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 the table that are in inventory on September 12, 2018 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: August 7, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

The meeting will be held as a teleconference call only and is open to the public to dial-in for participation. Individuals who plan to dial-in to the meeting and need special assistance or

other reasonable accommodations in order to do so, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Advisory Committee to the Director, National Institutes of Health.

*Date:* August 24, 2018.

*Time:* 9:15 a.m. to 9:45 a.m.

*Agenda:* Updates on ACD Working Groups.

*Place:* National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892 (Telephone Conference Call), 800-369-1915, Access Code: 6496247.

*Contact Person:* Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301-496-4272, [Woodgs@od.nih.gov](mailto:Woodgs@od.nih.gov).

This notice is being published less than 15 days prior to the meeting due to scheduling difficulties.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <http://acd.od.nih.gov>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: August 8, 2018.

**David D. Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection; 60-Day Comment Request; National Cancer Institute (NCI) Future Fellows Resume Databank

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health, National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**DATES:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Angela Jones, Program