

| 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.*

[FR Doc. 2018-17226 Filed 8-10-18; 8:45 am]

**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.*

[FR Doc. 2018-17345 Filed 8-10-18; 8:45 am]

**BILLING CODE 4140-01-P**

## 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

Coordinator, Center for Cancer Training, National Cancer Institute, 9609 Medical Center Drive, Room 2W-236, Bethesda, Maryland, 20892 or call non-toll-free number (240) 276-5659 or Email your request, including your address to: [jonesangel@mail.nih.gov](mailto:jonesangel@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**SUPPLEMENTARY INFORMATION:** Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3)

Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Proposed Collection Title:* National Cancer Institute Future Fellows Resume Databank, 0925-XXXX, Exp., Date XX/XXXX, EXISTING COLLECTION IN USE WITHOUT OMB NUMBER, National Cancer Institute (NCI), National Institutes of Health (NIH).

*Need and Use of Information Collection:* The National Cancer Institute, Center for Cancer Training mission is to catalyze the development of the 21st century workforce capable of advancing cancer research through a scientifically integrated approach. This is accomplished by, (1) coordinating and providing research training and career development activities for fellows

and trainees in NCI's laboratories, clinics, and other research groups, (2) developing, coordinating, and implementing opportunities in support of cancer research training, career development, and education at institutions nationwide, and (3) identifying workforce needs in cancer research and adapting NCI's training and career development programs and funding opportunities to address these needs. The proposed information collection involves a website to collect and maintain resumes of interested candidates to be considered for postdoctoral fellowships and internships in science. After posting their resume in the database, NCI Scientists can view and select candidates for current fellowship and internship opportunities offered at NCI.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden are 200 hours.

#### ESTIMATED ANNUALIZED BURDEN HOURS

| Form name                         | Type of respondent         | Number of respondents | Number of responses per respondent | Average time per response (in hours) | Total annual burden hours |
|-----------------------------------|----------------------------|-----------------------|------------------------------------|--------------------------------------|---------------------------|
| Resume Databank Application ..... | Postdoctoral Fellows ..... | 200                   | 2                                  | 30/60                                | 200                       |
| Total .....                       | .....                      | 200                   | 400                                | .....                                | 200                       |

Dated: July 24, 2018.

**Patricia M. Busche,**

*Project Clearance Liaison, National Cancer Institute, National Institutes of Health.*

[FR Doc. 2018-17339 Filed 8-10-18; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Center for Inherited Disease Research Access Committee.

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:* Center for Inherited Disease Research Access Committee.

*Date:* September 7, 2018.

*Time:* 8:30 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Center for Inherited Disease Research (CIDR), McHenry Conference Room, 1812 Ashland Avenue, Baltimore, MD 21205.

*Contact Person:* Barbara J. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Ste. 4076, MSC 9306, Bethesda, MD 20892-9306, 301-402-0838, [barbara.thomas@nih.gov](mailto:barbara.thomas@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: August 7, 2018.

**Sylvia L. Neal,**

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

[FR Doc. 2018-17340 Filed 8-10-18; 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 Meetings

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:* Environmental Health Sciences Review Committee; Environmental Health Sciences Core Centers P30 Clinical Trial Optional.

*Date:* August 21-22, 2018.