

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 089497	Imipramine HCl Tablets USP, 25 mg	Par Pharmaceutical Inc.
ANDA 089628	Leucovorin Calcium for Injection, EQ 50 mg base/vial	Pharmachemie USA Inc., 323 Davis St., Northborough, MA 01532.
ANDA 089681	Bromfed-DM (brompheniramine maleate, dextromethorphan hydrobromide, and pseudoephedrine HCl) Syrup, 2 mg/5 mL; 10mg/5 mL; 30mg/5 mL.	Wockhardt Bio AG, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053.
ANDA 089915	Leucovorin Calcium for Injection, EQ 100 mg base/vial	Pharmachemie USA Inc.
ANDA 090098	Tretinoin Cream USP, 0.0375%	Allergan Sales, LLC.
ANDA 090137	Irinotecan HCl Injection, 40 mg/2 mL and 100 mg/5 mL	Sandoz Inc.
ANDA 090190	Pramipexole Dihydrochloride Tablets, 0.125 mg, 0.25 mg, 0.5 mg, 0.75 mg, 1 mg, and 1.5 mg.	Do.
ANDA 090220	Adenosine Injection USP, 3 mg/mL	Wockhardt Limited, c/o Wockhardt USA LLC, 20 Waterview Blvd., 3rd Floor, Parsippany, NJ 07054.
ANDA 090300	Children's Cetirizine HCl Allergy and Hives Relief Oral Solution OTC, 5 mg/5 mL.	Cypress Pharmaceutical, Inc., 10 North Park Place, Suite 210, Morristown, NJ 07960.
ANDA 090751	Cetirizine HCl Oral Solution USP, 5 mg/5 mL	Aurobindo Pharma Limited.
ANDA 090985	Octreotide Acetate Preservative Free Injection EQ 0.05 mg base/mL, EQ 0.1 mg base/mL, and EQ 0.5 mg base/mL.	Wockhardt Limited.
ANDA 090986	Octreotide Acetate Injection EQ 0.2 mg base/mL and EQ 1 mg base/mL.	Do.
ANDA 091068	Ceftriaxone for Injection USP, EQ 10 g base/vial	Agila Specialties Private Limited, c/o Agila Specialties Inc., 201 South Main St., Suite 3, Lambertville, NJ 08530.
ANDA 091185	Topiramate Tablets USP, 25 mg, 50 mg, 100 mg, and 200 mg.	Hikma Pharmaceuticals.
ANDA 091293	Idarubicin HCl Injection, 1 mg/mL	Sandoz Inc.
ANDA 091299	Fluorouracil Injection USP, 2.5 g/50 mL and 5 g/100 mL	Do.
NDA 200045	Amtornide (aliskiren hemifumarate, amlodipine, and hydrochlorothiazide) Tablets.	Novartis Pharmaceuticals Corp.
ANDA 200146	Doxorubicin HCl Injection USP, 2 mg/mL	Sandoz Inc.
NDA 200199	Topotecan Injection, EQ 1 mg base/mL, EQ 3 mg base/3 mL, and EQ 4 mg base/4 mL.	Do.
ANDA 201211	Bromfenac Sodium Ophthalmic Solution, EQ 0.09% acid	Coastal Pharmaceuticals, 1240 Sugg Parkway, Greenville, NC 27834.
NDA 201917	Incivek (telaprevir) Tablets, 375 mg	Vertex Pharmaceuticals, Inc., 50 Northern Ave., Boston, MA 02210.
NDA 202088	Suprenza (phentermine HCl) Orally Disintegrating Tablets, 15 mg, 30 mg, and 37.5 mg.	Citius Pharmaceuticals, LLC, 11 Commerce Dr., First Floor, Cranford, NJ 07016.
ANDA 202209	Tretinoin Cream USP, 0.075%	Allergan Sales, LLC.
NDA 202513	Gelnique (oxybutynin) Gel, 3%	Do.
NDA 203595	Suclear (magnesium sulfate, polyethylene glycol 3350, potassium chloride, potassium sulfate, sodium bicarbonate, sodium chloride, and sodium sulfate) Oral Solution.	Braintree Laboratories, Inc.
NDA 204508	Clinolipid 20% (olive oil and soybean oil) USP, 16%/4%	Baxter Healthcare Corp.
NDA 206510	Dutrebis (lamivudine and raltegravir potassium) Tablets, 150 mg/EQ 300 mg base.	Merck Sharp & Dohme Corp.

Therefore, under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn. 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: June 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-12908 Filed 6-20-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[CFDA Number: 93.085]

Awards Unsolicited Proposal for the Professionalism and Integrity in Research Program

AGENCY: Office of Research Integrity, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice of award of a single-source unsolicited grant to Washington University in St. Louis, Missouri.

SUMMARY: The Office of Research Integrity (ORI) announces the award of a single-source, grant in response to an unsolicited proposal from Washington University, St. Louis, Missouri. The proposal submitted was not solicited either formally or informally by any federal government official.

FOR FURTHER INFORMATION CONTACT: Kathryn Partin at kathryn.partin@hhs.gov or by telephone at 240-453-8200.

SUPPLEMENTARY INFORMATION:

Recipient: Washington University, St. Louis, Missouri.

Purpose of the Award: Grant to provide remediation training through

the Professionalism and Integrity in Research Program (PI Program) to promote research integrity and prevent research misconduct.

Amount of Award: \$135,763 in Federal Fiscal Year (FFY) 2017 funds and estimated \$135,665 in FFY 2018 funds subject to the enactment of appropriations and availability of funds.

Project Period: July 1, 2017–June 30, 2019.

ORI performed an objective review of the unsolicited proposal from Washington University to expand and evaluate the Professionalism and Integrity in Research Program (PI Program), the only remediation program for researchers who violate expectations for the responsible conduct of research. Based on an external and internal review of the proposal, ORI determined that it has merit.

There is a strategic importance of access to this type of training. Research misconduct involving Public Health Service (PHS) support is contrary to the interests of PHS and the federal government, the health and safety of the public, the integrity of research, and the conservation of public funds. Participants in the PI Program will demonstrate better research compliance and integrity outcomes, such as developing better, more ethical research practices. These outcomes will promote research integrity and help prevent future research misconduct.

This award is being made non-competitively because there is no current, pending, or planned funding opportunity announcement under which this proposal could be competed. ORI has identified three additional key reasons to support rationale for awarding this unsolicited proposal:

1. ORI's federal regulation directs us to focus on remediation of Respondents who have been found to commit research misconduct, and the PI Program permits a pathway for that remediation after any sanctions have been completed.

2. Washington University is uniquely positioned to provide this type of training. As the only remediation program for researchers, the grantee has developed a comprehensive and intensive program that will improve research compliance and integrity outcomes.

3. With this experience, Washington University is well known in the research community and is an important service to PHS funded institutions. The program has a robust and unique process for assessment and data analysis.

Legislative Authority: Sec. 301 of the Public Health Service Act, 42 U.S.C. 241.

Kathryn M. Partin,

Director of the Office of Research Integrity.

[FR Doc. 2017–12514 Filed 6–20–17; 8:45 am]

BILLING CODE 4150–28–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 (5 U.S.C. App.), 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; Partnerships for Development of Vaccines to Prevent Mycobacterium Tuberculosis and or Tuberculosis Disease.

Date: July 18–20, 2017.

Time: 9:00 a.m. to 5:00 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: Amir E. Zeituni, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9834, Rockville, MD 20852, 301–496–2550, amir.zeituni@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: June 15, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–12873 Filed 6–20–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Clinical Trial (U01) Review.

Date: July 10, 2017.

Time: 4:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, Rockville, MD 20850, 301–402–3587, rayk@nidcd.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

Date: July 24, 2017.

Time: 10:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Shiguang Yang, DVM, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Room 8349, Bethesda, MD 20892, 301–496–8683, yangshi@nidcd.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: June 15, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–12875 Filed 6–20–17; 8:45 am]

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