

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](mailto:Stacy.Kane@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain

exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to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 in this document are no longer being marketed.

Application No.	Drug	Applicant
NDA 008883 .....	OPHTHAINE (proparacaine hydrochloride) Solution/Drops; Ophthalmic, 0.5%.	Apothecon, Inc.
NDA 009053 .....	PURINETHOL (mercaptapurine) Tablet; Oral, 50 milligrams (mg).	Teva Pharmaceuticals USA.
NDA 012427 .....	DIDREX (benzphetamine hydrochloride) Tablet; Oral, 50 mg	Pharmacia & Upjohn Co.
NDA 012583 .....	OPHTHETIC (proparacaine hydrochloride) Solution/Drops; Ophthalmic, 0.5%.	Allergan Pharmaceutical.
NDA 017716 .....	OVCON-35 (ethinyl estradiol; norethindrone) Tablet; Oral-28, 0.035 mg; 0.4 mg.	Warner Chilcott LLC.
NDA 018782 .....	NORDETTE-28 (ethinyl estradiol; levonorgestrel) Tablet; Oral-28, 0.03 mg; 0.15 mg.	Teva Branded Pharmaceutical Products R and D, Inc.
NDA 021199 .....	QUIXIN (levofloxacin) Solution/Drops; Ophthalmic, 0.5% .....	Santen, Inc.
NDA 021595 .....	SANCTURA (trospium chloride) Tablet; Oral, 20 mg .....	Allergan, Inc.
NDA 021664 .....	BROMDAY (bromfenac sodium) Solution/Drops; Ophthalmic, EQ 0.09% acid.	Bausch & Lomb, Inc.
NDA 022103 .....	SANCTURA XR (trospium chloride) Extended-Release Capsule; Oral, 60 mg.	Allergan, Inc.
ANDA 060571 ....	MYCOSTATIN (nystatin) Ointment; Topical, 100,000 units/gram (g).	Delcor Asset Corp.
ANDA 060575 ....	MYCOSTATIN (nystatin) Cream; Topical, 100,000 units/g .....	Do.
ANDA 060578 ....	MYCOSTATIN (nystatin) Powder; Topical 100,000 units/g .....	Do.
ANDA 063116 ....	TOBRAMYCIN SULFATE (PHARMACY BULK) (tobramycin sulfate) Injectable; Injection, EQ 40 mg base/milliliter.	Hospira, Inc.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document 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 NDAs and ANDAs listed in this

document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. 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: November 30, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-30628 Filed 12-3-15; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute on Drug Abuse;  
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 on Drug Abuse Special Emphasis Panel; R13 Conference Grant Review (PA 13–347).

*Date:* December 8, 2015.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Virtual Meeting).

*Contact Person:* Susan O. McGuire, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Blvd., Room 4245, Rockville, MD 20852, 301–435–1426. [mcguireso@mail.nih.gov](mailto:mcguireso@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 27, 2015.

**Natasha M. Copeland,**

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

[FR Doc. 2015–30603 Filed 12–3–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Drug Abuse 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Drug Abuse Special Emphasis Panel; Therapeutic Cannabidiol Pulmonary Delivery Device (8929).

*Date:* December 14, 2015.

*Time:* 8:00 a.m. to 12:30 p.m.

*Agenda:* To review and evaluate contract proposals.

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

*Contact Person:* Nadine Rogers, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4229, MSC 9550, Bethesda, MD 20892–9550, 301–402–2105, [rogersn2@nida.nih.gov](mailto:rogersn2@nida.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute on Drug Abuse Special Emphasis Panel; Pain Mobile Remote Pain Management System (4434).

*Date:* December 14, 2015.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate contract proposals.

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

*Contact Person:* Nadine Rogers, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4229, MSC 9550, Bethesda, MD 20892–9550, 301–402–2105, [rogersn2@nida.nih.gov](mailto:rogersn2@nida.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program No.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 27, 2015.

**Natasha M. Copeland,**

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

[FR Doc. 2015–30602 Filed 12–3–15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed project or

to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

#### Proposed Project—Strategic Prevention Framework State Incentive Grant (SPF SIG) Program, Cohorts IV and V—NEW

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) requests OMB approval to collect community outcomes data for the cross-site evaluation of the Strategic Prevention Framework State Incentive Grant (SPF SIG) program, Cohorts IV and V. CSAP has previously funded two cross-site evaluations of the Strategic Prevention Framework State Incentive Grant (SPF SIG), one focused on Cohorts I and II and the other on Cohorts III, IV, and V. Collectively, these evaluations provide an important opportunity to inform the prevention field on current practices and their association with community- and state-level outcomes.

Data are collected at the grantee, community, and participant levels. The collection of community outcomes data is the focus of the current request. The primary cross-site evaluation objective is to determine the impact of SPF SIG on building prevention capacity and infrastructure, and preventing the onset and reducing the progression of substance abuse, as measured by the SAMHSA National Outcome Measures (NOMs).

The SPF SIG grant program is a major investment by the federal government to improve substance abuse prevention systems and enhance the quality of prevention programs, primarily through the implementation of the SPF process. The goal of this initiative is to provide states, jurisdictions, tribal entities, and the communities within them with the tools necessary to develop an effective prevention system with attention to the processes, directions, goals, expectations, and accountabilities necessary for functionality. SAMHSA/