

default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committees will discuss new drug application (NDA) 209653, for oxycodone hydrochloride extended-release oral tablets, submitted by Intellipharmaceuticals Corp., with the proposed indication of management of moderate-to-severe pain when a continuous around-the-clock analgesic is needed for an extended period of time. The product has been formulated with properties intended to deter abuse, and the applicant has submitted data to support these abuse-deterrent properties for this product. The committees will be asked to discuss the overall risk-benefit profile of the product, and whether the applicant has demonstrated abuse-deterrent properties for their product that would support labeling.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: On July 26, 2017, from 9:15 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the docket (see **ADDRESSES**) on or before July 12, 2017, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those individuals interested in making formal oral presentations should notify

the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 3, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 5, 2017.

Closed Committee Deliberations: On July 26, 2017, from 8 a.m. to 9:15 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). During this session, the committees will discuss the drug development program of an investigational abuse-deterrent opioid product.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Stephanie L. Begansky at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 27, 2017.

Anna K. Abram,

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

[FR Doc. 2017-13887 Filed 6-30-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2016-N-2976; FDA-2016-N-3535; FDA-2013-N-1089; FDA-2013-N-1619; FDA-2013-N-0719; FDA-2016-N-3586; FDA-2013-N-0796; FDA-2016-N-0736; FDA-2016-N-3995; FDA-2013-D-0575; FDA-2016-N-0735]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, (301) 796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the Internet at <https://www.reginfo.gov/public/do/PRAMain>. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Request for Information From U.S. Processors That Export to the European Community	0910-0320	5/31/2020
Guidance for Industry: Special Protocol Assessment	0910-0470	5/31/2020
Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use	0910-0553	5/31/2020
Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements	0910-0606	5/31/2020
Guidance for Industry: Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products	0910-0675	5/31/2020

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control No.	Date approval expires
Focus Groups About Drug Products as Used by the Food and Drug Administration	0910-0677	5/31/2020
Testing Communication on Medical Devices and Radiation-Emitting Products	0910-0678	5/31/2020
Tracking Network for PETNet, LivestockNet, and SampleNet	0910-0680	5/31/2020
Medical Devices: Pediatric Uses of Devices; Requirements for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device is Intended to Treat, Diagnose, or Cure	0910-0748	5/31/2020
Guidance for Industry: Expedited Programs for Serious Conditions—Drugs and Biologics	0910-0765	5/31/2020
Superimposed Text in Direct-to-Consumer Promotion of Prescription Drugs	0910-0831	5/31/2020

Dated: June 27, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning,
Legislation, and Analysis.

[FR Doc. 2017-13890 Filed 6-30-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary’s Advisory Committee on Human Research Protections

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

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, notice is hereby given that the Secretary’s Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP Web site at: <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

DATES: The meeting will be held on Tuesday, July 25, 2017, from 8:30 a.m. until 5:00 p.m., and Wednesday, July 26, 2017, from 8:30 a.m. until 2:30 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; email address: SACHRP@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on

issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 8:30 a.m., on Tuesday, July 25, 2017, followed by opening remarks from Dr. Jerry Menikoff, Director, Office for Human Research Protections and Dr. Stephen Rosenfeld, SACHRP Chair. (<https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/html/2017-01058.htm>).

The SOH will present their recommendations regarding the new Common Rule’s compliance dates and transition provisions, as well as for the interpretation and implementation of the broad consent provision, followed by the SAS discussing their report on the interpretation of the new exemption involving benign behavioral interventions. The Tuesday, July 25, meeting will adjourn at approximately 5:00 p.m.

The Wednesday, July 26, meeting will begin at 8:30 a.m. with discussion of recommendations from the SAS regarding the new Common Rule’s expedited review requirements.

The meeting will adjourn at approximately 2:30 p.m., July 26, 2017. Time for public comment sessions will be allotted both days. On-site registration is required for participation in the live public comment session. Note that public comment must be relevant to issues currently being addressed by the SACHRP. Individuals submitting written statements as public

comment should email or fax their comments to SACHRP at SACHRP@hhs.gov at least five business days prior to the meeting.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting.

Dated: June 27, 2017.

Julia G. Gorey,
Executive Director, Secretary’s Advisory Committee on Human Research Protections.

[FR Doc. 2017-13932 Filed 6-30-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Stakeholder Listening Session on Strategies for Improving Parity for Mental Health and Substance Use Disorder Coverage

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public stakeholder listening session on Strategies for Improving Parity for Mental Health and Substance Use Disorder Coverage. The public meeting, mandated in the 21st Century Cures Act, seeks public comment on improved Federal and State coordination related to section 2726 of the Public Health Service Act, section 712 of the Employee Retirement Income Security Act of 1974, section 9812 of the Internal Revenue Code of 1986, and any comparable provisions of State law. The public meeting will seek participation from the required stakeholders in statute, State health commissioners, State agencies, State attorneys general, the National Association of Insurance Commissioners, health insurance issuers, providers of mental health and