

Dated: October 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-27340 Filed 11-8-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anesthetic and Analgesic Drug Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

DATES: *Date and Time:* The meeting will be held on December 7, 2012, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20992-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Philip A. Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email:

AADPAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/>

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.

Agenda: The committee will discuss the risks and benefits of new drug application (NDA) 202880, by Zogenix Inc., for hydrocodone bitartrate extended-release capsules (proposed tradename ZOHYDRO ER), an opioid analgesic medication for the management of moderate to severe chronic pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. This formulation of hydrocodone bitartrate extended-release capsules represents the first single-entity (i.e., containing no other active pharmaceutical ingredients, such as acetaminophen or ibuprofen) hydrocodone-containing drug product. It will be formulated in dose strengths up to 50 milligrams, and administered twice daily (i.e., every 12 hours). The committee will be asked to determine whether the benefit-risk assessment of this product favors its approval for marketing.

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 <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 23, 2012. Oral presentations from the public will be scheduled between approximately 1 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 November 14, 2012. 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 November 15, 2012.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact Philip Bautista 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 <http://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: November 5, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012-27368 Filed 11-8-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Ethical Dilemmas in Surgery and Utilization of Hospital Ethics Consultation Service: A Survey

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Clinical Center Department of Bioethics, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 28, 2011 on page 72955-72956 [FR DOC # 2011-30548] and allowed 60-days for public comment. Two comments were received by the NIH Department of Bioethics. The comments we received included one request from a survey firm that was interested in possibly administering the survey, and one

request from the American Association of Medical Colleges (AAMC) that was interested in knowing what items were in the survey instrument. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Ethical Dilemmas in Surgery and Utilization of Hospital Ethics Consultation Service: A Survey. Type of Information Collection Request: NEW. Need and Use of Information Collection: This survey is

intended to collect information about the ethical dilemmas that surgeons have faced in their practices over the past year, and assess their experiences, if any, with their hospital consultation services. Specifically, the information gathered in this study will be valuable in understanding the ethical dilemmas that surgeons face, the utility of institution ethics consultations services for surgeons, and to identify what barriers, if any, discourage surgeons from utilizing these services. The results of this study can be used by medical professionals, hospitals, and bioethicists in several important ways. First, they will provide a better understanding the ethical dilemmas that surgeons face in

their practices. Second, they will provide understanding of factors that determine the current utilization of hospital consultation services by surgeons. Third, information collected on the barriers to surgeons' use of ethics consultation services will provide better insight into the perspective and culture of surgery as it relates to ethical dilemmas in their practices and how ethics consultation services could better support surgeons when faced with these dilemmas. **Frequency of Response:** Once. **Affected Public:** Individuals; Businesses or other for-profit. **Type of Respondents:** Individuals.

The annual reporting burden is as follows:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Estimated total annual burden hours requested
Surgeons	598	1	15/60	150
Total	598	150

There are no capital, operating, or maintenance costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Marion

Danis, MD, Department of Clinical Bioethics, National Institutes of Health, Building 10, Room 1C118, Bethesda, MD 20892-1156; Telephone: 301-435-8727; Facsimile: 301-496-0760; Email: mdanis@cc.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: August 28, 2012.

Laura Lee,
Project Clearance Liason, CC, National Institutes of Health.
[FR Doc. 2012-27445 Filed 11-8-12; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected

inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Cell Lines Expressing Nuclear and/or Mitochondrial RNase H1

Description of Technology: RNase H1 has been shown to remove RNA/DNA hybrids and either too much or too little enzyme can lead to undesirable effects such as deletions of DNA. The gene encoding RNase H1 in mammalian cells produces two forms of the protein. One is targeted to the nucleus of the cell and the other to the mitochondrial organelle. To study the effects of expression as well as to understand the regulation of the frequency with which each form is made, NIH investigators constructed cells derived from HEK293 cells where expression of each or both forms is/are expressed only after addition of doxycycline as a small molecule inducer compound. The set of cell lines could be important in the process of analysis of RNA/DNA hybrids as each