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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-D-1057]

#### Draft Guidance for Industry and Food and Drug Administration Staff; Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices." This draft guidance is to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of highly multiplexed microbiological/medical countermeasures in vitro nucleic acid based diagnostic devices (HMMDs) intended to simultaneously detect and identify multiple pathogen nucleic acids extracted from a single appropriate human specimen or culture. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 7, 2013.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

[www.regulations.gov](http://www.regulations.gov). Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** John Hobson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5555, Silver Spring, MD 20993-0002, 301-796-5892.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

This draft guidance is to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of HMMDs intended to simultaneously detect and identify multiple pathogen nucleic acids extracted from a single appropriate human specimen or culture. For the purposes of this draft guidance document the multiplex level that is used to define HMMDs is the capability to detect  $\geq 20$  different organisms/targets, in a single reaction, using a nucleic acid based technology and involves testing multiple targets through a common process of specimen preparation, amplification and/or detection, and result interpretation. HMMDs are used to aid in the diagnosis of infection.

The scope of this draft guidance includes nucleic acid based devices that employ technologies such as polymerase chain reaction, reverse-transcriptase polymerase chain reaction, bead-based liquid arrays, microarrays, re-sequencing approaches as well as the measurement of individual targets determined by  $\geq 20$  separate assays that are reported out simultaneously through the use of a diagnostic algorithm. This draft guidance is not intended to address devices that utilize detection mechanisms other than nucleic acid based approaches. The document does not apply to devices that are intended to screen donors of blood and blood components, and donors of human cells, tissues, and cellular and tissue-based products for communicable diseases.

##### **II. Significance of Guidance**

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on highly multiplexed microbiological/medical countermeasure in vitro nucleic acid based diagnostic devices. It does

not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

##### **III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices," you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1803 to identify the guidance you are requesting.

##### **IV. Paperwork Reduction Act of 1995**

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073.

##### **V. Comments**

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: October 31, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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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](mailto: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.*

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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