

Dated: December 23, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Cardiovascular and Renal Drugs 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:* Cardiovascular and Renal Drugs Advisory Committee.

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

*Date and Time:* The meeting will be held on February 23, 2012, from 8 a.m. to 5 p.m.

*Location:* Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's telephone number is (301) 589-5200.

*Contact Person:* Kristina Toliver, 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: [CRDAC@fda.hhs.gov](mailto:CRDAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1 (800) 741-8138 ((301) 443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* The committee will discuss new drug application (NDA) 203202, proposed trade name NORTHERA (droxidopa capsules), submitted by Chelsea Therapeutics, Inc., for the

treatment of symptomatic neurogenic orthostatic hypotension in patients with primary autonomic failure (Parkinson's Disease, Multiple System Atrophy, and Pure Autonomic Failure), Dopamine Beta-Hydroxylase Deficiency, and Non-Diabetic Autonomic Neuropathy.

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 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 February 8, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 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 January 31, 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 February 1, 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 Kristina Toliver 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: December 23, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-33561 Filed 12-29-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Oncologic Drugs 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:* Oncologic Drugs Advisory Committee.

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

*Date and Time:* The meeting will be held on February 8, 2012, from 8 a.m. to 12:30 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. 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:* Caleb Briggs, 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: [ODAC@fda.hhs.gov](mailto:ODAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1 (800) 741-8138 ((301) 443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

**Agenda:** The committee will discuss supplemental biologics license application 125320/28 for XGEVA (denosumab) injection, application submitted by Amgen Inc. The proposed indication (use) for this product is for the treatment of men with castrate-resistant prostate cancer at high risk of developing bone metastases, or spread of cancer to the bones.

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 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 January 25, 2012. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11:30 a.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 January 17, 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 January 18, 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 Caleb Briggs 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: December 22, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-33548 Filed 12-29-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0247]

#### Food and Drug Administration Transparency Initiative: Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency; Availability

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

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** As part of the Transparency Initiative, the Food and Drug Administration (FDA or Agency) is announcing the availability of a report entitled "Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency." This report was prepared in response to Action Item 11 in the *Phase III Report* (FDA Transparency Initiative: Improving Transparency to Regulated Industry, dated January 2011). In that action item, the Commissioner of Food and Drugs (the Commissioner), Dr. Margaret A. Hamburg, called for a cross-Agency working group to prepare a report identifying FDA's "best practices" and making recommendations to streamline the development of guidance documents, reduce the time between issuing draft and final guidance documents, and make it easier to find guidance documents on FDA's Web site.

**DATES:** Submit either electronic or written comments by February 28, 2012.

**ADDRESSES:** Submit electronic comments to <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. All comments should be identified with the docket number found in brackets at the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Lisa M. Dwyer, Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4228, Silver Spring, MD 20993, (301) 796-4820, FAX: (301) 847-8616, [lisa.dwyer@fda.hhs.gov](mailto:lisa.dwyer@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On January 21, 2009, President Obama issued a memorandum urging the heads of executive departments and Agencies to create an "unprecedented level of openness" to "strengthen our democracy and promote efficiency and effectiveness" (see *Memorandum to Heads of Executive Departments and Agencies on Transparency and Open Government*, January 21, 2009, (74 FR 4685, January 26, 2009)). In response, the following June FDA launched its Transparency Initiative. Information on the FDA Transparency Initiative is available at <http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/default.htm>.

As part of this initiative, FDA issued the *Phase III Report* (FDA Transparency Initiative: Improving Transparency to Regulated Industry, dated January 2011) in January 2011. The *Phase III Report* contained 19 action items and 5 draft proposals to make FDA's operations and decisionmaking processes more transparent and to foster more efficient and cost-effective regulatory processes. In Action Item 11 of the *Phase III Report*, the Commissioner called for a cross-Agency working group to prepare a report identifying FDA's "best practices" and making recommendations to: (1) Streamline the development of guidance documents, (2) reduce the time between issuing draft and final guidance documents, and (3) make it easier to find guidance documents on FDA's Web site.

In response to that action item, a cross-Agency working group under the leadership of the Office of Policy in the Office of the Commissioner prepared a report entitled "Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency" (GGP