study (an in vivo fasting study) to demonstrate BE of generic nitroglycerin metered spray/sublingual products and generic nitroglycerin metered aerosol/sublingual products. In both of the revised draft guidances, FDA notes that even though we have not requested comparative in vitro studies, in vitro studies outlined in the 2002 guidance for industry, ''Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products—Chemistry, Manufacturing, and Controls Documentation,'' should still be submitted for chemistry, manufacturing, and controls evaluation.

In December 2010, G. Pohl-Boskamp GmbH and Company KG (Pohl), manufacturer of the RLD Nitrolingual Pumpspray, filed a citizen petition challenging FDA's Draft Nitroglycerin Spray BE Recommendations of February 2010 (Docket No. FDA–2010–P–0648). FDA is reviewing the issues raised in the petition and will consider any comments on the Revised Draft Nitroglycerin Spray BE Recommendations before responding to Pohl's citizen petition and finalizing its BE recommendation for nitroglycerin metered spray/sublingual products.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidances, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for nitroglycerin metered spray/sublingual products and nitroglycerin metered aerosol/sublingual products. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

III. Electronic Access

Persons with access to the Internet may obtain the documents at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: February 7, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–3233 Filed 2–10–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Gastrointestinal 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Gastrointestinal 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 March 13, 2012, from 8 a.m. to 5 p.m.

Location: Hilton Washington, DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301–589–5200.

Contact Person: Nicole Vesely, 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, email: *GIDAC@fda.hhs.gov,* FAX: 301–847–8533, 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 and provide general advice on the appropriate target populations, objectives and designs of trials intended to evaluate products for the control of hyperbilirubinemia (increased levels of bilirubin in the body) in newborn infants.

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: On March 13, 2012, from 8 a.m. to 12:30 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 committee. Written submissions may be made to the contact person on or before February 28, 2012. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. 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 February 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 February 21, 2012.

Closed Presentation of Data: On March 13, 2012, from 1:15 p.m. to 5 p.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 committee will discuss the drug development program of an investigational drug.

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 Nicole

Vesely 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: February 7, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–3203 Filed 2–10–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0102]

Antiparasitic Drug Use and Resistance in Ruminants and Equines; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Antiparasitic Drug Use and Resistance in Ruminants and Equines.'' The purpose of the meeting is to discuss the current state of anthelmintic resistance in the United States and worldwide, tools for the evaluation of antiparasitic resistance, evaluation of the effectiveness of drugs against resistant parasites, and the scientific rationale for the use of combinations of antiparasitic drugs in ruminants and equines.

DATES: *Date and Time:* The public meeting will be held on March 5 and 6, 2012, from 8 a.m. to 5:30 p.m.

Location: The meeting will be held at the Hilton Washington, DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852–1699; 1–800–774–1500; FAX 301–468–0163; *http://rockvillehotel-px.rtrk.com/.*

Contact Person: Aleta Sindelar, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9004, FAX: 240–276–9030, email: *Aleta.Sindelar@fda.hhs.gov.*

Requests for Oral Presentations and Registration: Interested persons may present data, information, or views, orally or in writing, on the topic of the discussion of the meeting. Written submissions may be made to the contact person on or before February 27, 2012. Oral presentations from the public during the open public comment period will be scheduled between approximately 2 p.m. and 3 p.m. on March 5, 2012, and 10:30 a.m. and 12 noon on March 6, 2012. Those desiring to make oral presentations should notify the contact person by February 20, 2012, and submit a brief statement of the general nature of information they wish to present and an indication of the approximate time requested to make their presentation. Time allotted for each presentation may be limited. The contact person will inform each speaker of their schedule prior to the meeting.

Registration is not required for this meeting; however, early arrival is recommended because seating may be limited. If you need special accommodations due to a disability, please contact Aleta Sindelar, (see *Contact Person*) at least 7 days in advance.

Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding this document. 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. 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. The docket will remain open for written or electronic comments for 60 days following the meeting.

SUPPLEMENTARY INFORMATION: The main purpose of the meeting is to explore and discuss ways in which antiparasitic drugs can be used, alone or in combination, to maximize antiparasitic drug efficacy and minimize parasitic resistance in ruminant and equine species. Other topics for discussion include:

(1) The current state of anthelmintic resistance in the United States and in other parts of the world;

(2) The factors that have contributed to the development of anthelmintic resistance;

(3) The role of refugia in the management of anthelmintic resistance;

(4) The use of mathematical modeling as a tool for evaluating resistance;

(5) The use of the fecal egg count reduction test in the detection and management of anthelmintic resistance; and

(6) Ways to maximize the effectiveness of anthelmintics for today and the future.

Agenda: The meeting will allow for public comment and discussion on current challenges regarding the use of antiparasitic drugs in ruminants and equines. The agenda for the public meeting will be made available on the Agency's Web site at *http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/default.htm.*

Transcripts: FDA will prepare a meeting transcript and make it available on the Agency's Web site (see *Agenda*) after the meeting. FDA anticipates that transcripts will be available approximately 30 business days after the meeting. The transcript will be available for public examination at the Division of Dockets Management (see *Comments* section of this document), between 9 a.m. and 4 p.m., Monday through Friday. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: February 7, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–3221 Filed 2–10–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Blood Products Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Blood Products Advisory Committee scheduled for February 29, 2012 is cancelled. This meeting was announced in the **Federal Register** of January 30, 2012 (77 FR 4567). FDA intends to convene at a future date a public scientific workshop to discuss the evaluation of possible new plasma products manufactured following storage at room temperature for up to 24 hours.

FOR FURTHER INFORMATION CONTACT: Bryan Emery or Pearl Muckelvene,