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 rifaximin-200 and rifaximin-550. 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. It is no longer necessary to send two copies of mailed 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. 2012–3234 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–2007–D–0369]

Draft Guidance for Industry on Bioequivalence Recommendation for Nitroglycerin Metered Spray/Sublingual Products and Metered Aerosol/Sublingual Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two draft guidances for industry entitled ''Bioequivalence Recommendations for Nitroglycerin,'' one for nitroglycerin metered spray/sublingual products and one for nitroglycerin metered aerosol/sublingual products. The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for these products. The draft guidances are revised versions of previously published draft guidances on the subject.

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 the draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft guidances by April 13, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance documents.

Submit electronic comments on the draft guidances 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.

FOR FURTHER INFORMATION CONTACT: Doan T. Nguyen, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–8608.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** sof June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry, ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This document announces the availability of two revised draft BE recommendations, one for nitroglycerin metered spray/sublingual products and one for nitroglycerin metered aerosol/sublingual products.

Nitrolingual Pumpspray (nitroglycerin lingual spray), approved by FDA in October 1985, is a metered dose spray indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease. Nitromist (nitroglycerin lingual aerosol), approved by FDA in November 2006, is another metered dose spray indicated for acute relief of an attack or acute prophylaxis of angina pectoris due to coronary artery disease. Nitrolingual Pumpspray and Nitromist are designated as reference listed drugs (RLDs), and therefore any ANDAs for generic nitroglycerin lingual spray or generic nitroglycerin lingual aerosol must demonstrate BE to the relevant RLD prior to approval. There are no approved ANDAs for these products.

In February 2010, FDA posted on its Web site a draft guidance for industry on the Agency's recommendations for BE studies to support ANDAs for nitroglycerin metered spray/sublingual products (Draft Nitroglycerin Spray BE Recommendations of February 2010). In that draft guidance, FDA recommended three studies to demonstrate BE of generic nitroglycerin metered spray/sublingual products: An in vivo fasting study, an in vitro study of unit dose and uniformity of unit dose, and an in vitro study of priming and tail off.

In March 2010, FDA posted on its Web site a draft guidance for industry on the Agency's recommendations for BE studies to support ANDAs for nitroglycerin metered aerosol/sublingual products (Draft Nitroglycerin Aerosol BE Recommendations of March 2010). In that draft guidance, FDA recommended three studies to demonstrate BE of generic nitroglycerin metered aerosol/sublingual products: An in vivo fasting study, an in vitro study of unit dose and uniformity of unit dose, and an in vitro study of priming and tail off.

FDA has reconsidered the recommendations for both of these draft guidances and has decided to revise them. In November 2011, FDA withdrew the Draft Nitroglycerin Spray BE Recommendations of February 2010 and the Draft Nitroglycerin Aerosol BE Recommendations of March 2010. FDA is now issuing revised draft guidances for industry on BE recommendations for nitroglycerin metered spray/sublingual products (Revised Draft Nitroglycerin Spray BE Recommendations) and nitroglycerin metered aerosol/sublingual products (Revised Draft Nitroglycerin Aerosol BE Recommendations). In these revised draft guidances, FDA recommends one

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

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Dated: February 7, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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

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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