DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1999–N–0082 (Formerly Docket No. 1999N–2079)]

Guidance for Industry on Reproductive and Developmental Toxicities—Integrating Study Results To Assess Concerns; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Reproductive and Developmental Toxicities—Integrating Study Results to Assess Concerns.'' This guidance describes an approach to estimating possible human developmental or reproductive risks associated with drug or biological product exposure when a nonclinical finding of toxicity has been identified, but definitive human data are unavailable. The guidance is intended for drug developers planning to submit new drug applications (NDAs) and biologics licensing applications (BLAs), and who are assessing nonclinical toxicity information.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance 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 guidance document.

Submit electronic comments on the guidance 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: Abigail Jacobs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 22, Rm. 6484, Silver Spring, MD 20993–0002, 301–796–0174.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Reproductive and Developmental Toxicities—Integrating Study Results to Assess Concerns.'' This guidance describes an approach to estimating possible human developmental or reproductive risks associated with drug or biological product exposure when a finding of toxicity has been identified, but definitive human data are unavailable. The guidance is intended for drug developers intending to submit NDAs and BLAs, and who are assessing nonclinical toxicity information. The recommendations included here will also help to ensure a consistent review of reproductive and developmental toxicity data among Center for Drug Evaluation and Research review staff.

This guidance does not: (1) Give detailed advice about labeling or placement of toxicity information in product labeling (for information on labeling, see 21 CFR 201.57); or (2) discuss clinical data, the integration of nonclinical and clinical data, or the clinical implications of these data.

The approach presented here for assessing nonclinical reproductive and developmental toxicity data involves the integration and careful consideration of a variety of different types of nonclinical information: Reproductive toxicology; general toxicology; and toxicokinetic and pharmacokinetic information, including absorption, distribution, metabolism, and elimination findings. The approach is used when there is a toxicity finding and focuses on assessing the likelihood that a drug will increase the risk of adverse human developmental or reproductive outcomes. The approach includes noting when studies were not conducted or when they were not performed using relevant model systems or at appropriate dose ranges.

On November 13, 2001 (66 FR 56830), FDA issued a draft of this guidance. Comments were received and carefully considered during the finalization of the guidance. Most changes to the document are editorial. However, one important change has been made. The description of a process that involved assignment of values of +1, −1 or 0 to the various factors was removed from the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on integration of study results to assess concerns about human reproductive and developmental toxicities. 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 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 document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 19, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24431 Filed 9–22–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management 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 Committees: Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee.

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

Date and Time: The meeting will be held on December 9, 2011, from 8 a.m. to 5 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College (UMUC), The Ballroom, 3501 University Blvd.,

East, Adelphi, MD. The conference center telephone number is 301–985–7300.

Contact Person: Kalyani Bhatt, 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, e-mail: *ACRHD@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: On December 9, 2011, the committees will discuss the benefits and risks of ORTHO EVRA (norelgestromin/ethinyl estradiol transdermal system), marketed by Janssen Pharmaceuticals, Inc., for the prevention of pregnancy. Specifically, the committees will discuss the possibly increased risk of thrombotic (blood clots) and thromboembolic events (blood clots that can break loose and move within the circulatory system) in users of ORTHO EVRA compared to women who use commonly prescribed birth control pills, as suggested by postmarketing studies.

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 November 23, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 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 November 15, 2011. 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 16, 2011.

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 Kalyani Bhatt 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: September 19, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–24533 Filed 9–22–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management 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 Committees: Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee.

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

Date and Time: The meeting will be held on December 8, 2011, from 8 a.m. to 5 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College, The Ballroom, 3501 University Blvd. East, Adelphi, MD. The conference center telephone number is 301–985–7300.

Contact Person: Kalyani Bhatt, 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, e-mail: *ACRHD@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: On December 8, 2011, the committees will discuss the benefits and risks of drospirenone-containing oral contraceptives in light of the emerging safety concern that the risk of venous thromboembolism (blood clots that can break loose and move within the circulatory system) associated with use of these products may be higher compared to oral contraceptives that contain the progestin, levonorgestrel. Drospirenone-containing oral contraceptives for the primary indication of pregnancy prevention include: YASMIN, YAZ (drospirenone/ethinyl estradiol tablets), BEYAZ, SAFYRAL (drospirenone/ethinyl estradiol/levomefolate calcium tablets and levomefolate calcium tablets), Bayer HealthCare, and the generic equivalents for these products.

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