DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Women's Health Dialogue; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration's (FDA) Office of Women's Health is announcing the following meeting: Women's Health Dialogue. The topics to be discussed are: Women in clinical trials, product safety, and consumer education and outreach.

Date and Time: The meeting will be held on April 18, 2001, from 10:30 a.m. to 5:30 p.m.

Location: Humbert Humphrey Bldg., 200 Independence Ave. NW., Washington, DC.

Contact: Gwen Jones, Office of Women's Health, 301–827–3369, FAX: 301–827–0926. Space is limited. Please contact Gwen Jones by April 13, 2001.

If you need special accommodations due to a disability, please contact Gwen Jones at least 7 days in advance.

Dated: March 29, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1852]

Draft ''Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997.'' This draft guidance provides recommendations on procedures, content, and format for submitting a postmarketing study status report for an approved human drug or licensed biological product; timeframes for FDA's review of postmarketing studies; and information about postmarketing studies that will be available to the public. The draft guidance is intended to assist applicants in meeting the requirements of section 130 of the Food and Drug Administration Modernization Act of 1997.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by July 3, 2001. Submit written comments on the information collection provisions by June 4, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling CDER at 301–827–4573 or the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION**: section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Sharon T. Risso, Center for Biologics Evaluation and Research (HFM–500), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–5098; or

James L. Cobbs, Center for Drug Evaluation and Research (HFD–102), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5610.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997.'' Section 506B (''Reports of Postmarketing Studies'') of the Federal Food, Drug, and Cosmetic Act (the act, 21 U.S.C. 356b) provides FDA with additional authority for monitoring the progress of postmarketing studies that drug and biologics applicants have made a commitment to conduct. Postmarketing studies are those studies conducted after approval to gather information about approved drug or biologics products. Such studies are used to gather additional information about product safety, efficacy, or optimal use.

Under 506B(a) of the act, an applicant who has entered into an agreement with FDA to conduct a postmarketing study is required to provide the agency with an annual report on the status of the study until the study is completed or terminated. The annual report must address the progress of the study or the reasons for the failure of the applicant to conduct the study. Section 506B(c) of the act directs FDA to develop and publish annually in the **Federal Register** a report on the status of postmarketing studies that applicants have made a commitment to conduct and for which status reports have been submitted. In the **Federal Register** of October 30, 2000 (65 FR 64607), the agency published a final rule to implement section 506B of the act. The final rule makes several changes to the existing regulations for approved human drugs and licensed biological products.

This draft guidance, when finalized, is intended to provide information on the following: (1) Procedures concerning the submission of postmarketing study status reports; (2) the content and format of a postmarketing study status report; (3) timeframes for FDA's review of postmarketing study reports; and (4) information about postmarketing studies that will be available to the public. This draft guidance would be applicable to postmarketing studies for approved human drug products and licensed biological products that meet the definition of ''drug'' under the act. It would not apply to biological products that meet the definition of medical ''device'' under the act; or to veterinary drug products, which will be addressed separately.

The draft guidance is being issued consistent with FDA's good guidance