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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0549]

Guidance for Industry on Advisory Committees: Implementing Section 120 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 guidance for industry entitled "Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997." This document provides guidance for industry on changes to the policies and procedures being used by the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) with regard to advisory committees as a result of section 120 of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act).

DATES: Written comments on the guidance may be submitted by *(insert date 90 days after date of publication in Federal Register)*. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at "http://www.fda.gov/cder/guidance/index.htm" or "http://www.fda.gov/cber/guidelines.htm". Submit written requests for single copies to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration,

5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document. After the comment period, comments may be submitted to one of the centers at the address below.

FOR FURTHER INFORMATION CONTACT:

Andrea C. Masciale, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5648, or

William Freas, Center for Biologics Evaluation and Research (HFM-21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled "Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997." Advisory committees provide independent advice and recommendations to FDA on scientific and technical matters related to the development and evaluation of products regulated by the agency. CDER and CBER request advice from advisory committees on a variety of matters, including various aspects of clinical investigations and applications for marketing approval of drug products. Although the committees provide recommendations to the agency, final decisions are made by FDA.

On November 21, 1997, President Clinton signed the Modernization Act. Section 120 of the Modernization Act amends section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) by adding section 505(n), which pertains to advisory committees that provide scientific advice and recommendations to the agency regarding the clinical investigation of drugs and the approval for marketing of drugs. Section 505(n) of the act includes provisions for: (1) Additional members to be included in new advisory committees, (2) new conflict of interest considerations, (3) education and training for new committee members, (4) timely committee consideration of matters, and (5) timely agency notification to affected persons of decisions on matters considered by

advisory committees. This guidance document explains how CDER and CBER intend to change their policies and procedures with regard to advisory committees to implement section 120 of the Modernization Act. Because CDER and CBER advisory committees are organized according to general subject (e.g., blood products, cardiovascular and renal drugs) and not according to the topic for consideration by the committee (e.g., a clinical investigation of a drug product, the content of a guidance document), CDER and CBER generally use the same policies and procedures for all advisory committees, regardless of the topic that will be considered by the committee. Therefore, unless otherwise stated, the guidance applies to CDER and CBER advisory committees regardless of the topic that will be considered by the committee. This guidance document is being issued as a level 1 guidance consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It is being implemented immediately without prior public comment because the guidance is needed to implement the Modernization Act. However, the agency wishes to solicit comments from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance represents the agency's current thinking on the advisory committee provisions of section 120 of the Modernization Act. 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 statute, regulations, or both.

Interested persons may, on or before *(insert date 60 days after date of publication in the Federal Register)*, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

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