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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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[Docket No. 00D-0084]

Guidance for Industry on Special Protocol Assessment; 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 "Special Protocol Assessment." This guidance provides guidance for industry on procedures adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, 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, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, FAX 888-CBERFAX or 301-827-3844. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to

<http://www.fda.gov/dockets/ecomments>. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Kim M. Colangelo, Center for Drug Evaluation and Research (HFD-2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5400, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0373.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 9, 2000 (65 FR 6377), FDA announced the availability of a draft version of this guidance for industry entitled “Special Protocol Assessment.” The agency has finalized that draft guidance after considering comments received on the draft guidance version. Eight comments were received, and minor changes were made to the draft guidance version in an effort to make the document more clear.

Section 119(a) of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Public Law 105-115) amends section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and directs FDA to allow sponsors to request special protocol assessment and for the agency to act on such requests. Moreover, in conjunction with the reauthorization of the Prescription Drug User Fee Act of 1992 in November 1997, FDA agreed to specific performance goals for special protocol assessment

and agreement. The performance goals are summarized in an enclosure to a letter dated November 12, 1997, from the then Secretary of Health and Human Services, Donna E. Shalala, to Senator James E. Jeffords.

The procedures and policies described in this guidance were adopted by CDER and CBER for evaluating issues related to the adequacy (e.g., design, conduct, analysis) of proposed studies. These procedures will implement section 119(a) of the Modernization Act and are consistent with the timeframes described in the performance goals.

In the **Federal Register** document (65 FR 6377) announcing the availability of the draft version of this guidance, FDA published the proposed collection of information related to the draft guidance. The document also requested comments on the burden estimates for the draft guidance. In the **Federal Register** of May 29, 2001 (66 FR 29147), the agency announced that it was submitting the collection of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guidance have been approved under OMB control number 0910-0470. This approval expires July 31, 2004. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This level 1 guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The guidance represents the agency's current thinking on special protocol assessment in CDER and CBER. 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

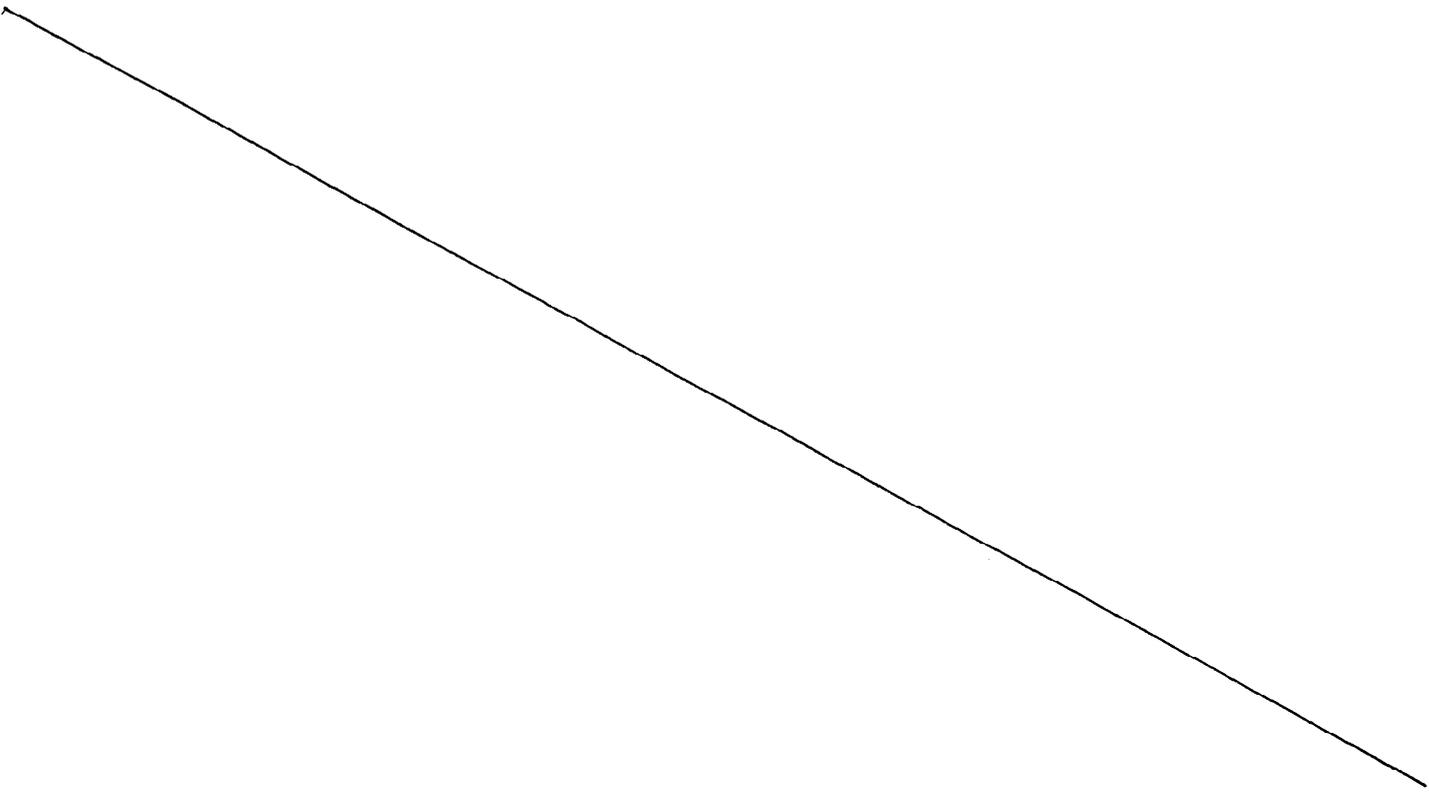
the requirements of the applicable statutes and regulations. The guidance will be updated as appropriate.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

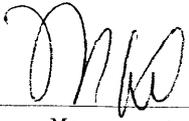
III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder.guidance/index.htm>, or <http://www.fda.gov/cber/guidelines.htm>.



Dated: 5/6/2
May 6, 2002.

cd0055



Margaret M. Dotzel,
Associate Commissioner for Policy.

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