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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0656]

Guidance for Industry on Submission of Abbreviated Reports and Synopses in Support of Marketing Applications; 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 "Submission of Abbreviated Reports and Synopses in Support of Marketing Applications." This guidance, which implements section 118 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act), is intended to assist applicants who wish to submit abbreviated reports and synopses in lieu of full reports for certain clinical studies, both in marketing applications for new products and in supplements to approved applications. The guidance describes which studies may be submitted as abbreviated reports or synopses and describes a format for such submissions.

DATES: General comments on 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 of the guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or the Manufacturers Assistance and Communication Staff (HFM-42), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-

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305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857.

Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Debbie J. Henderson, Center for Drug Evaluation and Research (HFD-6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6779.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 21, 1998 (63 FR 50251), FDA announced the availability of a draft version of this guidance for industry entitled “Submission of Abbreviated Reports and Synopses in Support of Marketing Applications.” The agency has finalized that draft guidance after considering comments received on the draft version. Only few comments were received, and minor changes were made to the draft version in an effort to make the document clearer.

This guidance implements section 118 of the Modernization Act, “Data requirements for drugs and biologics,” which directs FDA to issue guidance on when abbreviated study reports may be submitted in new drug applications (NDA’s) and biologics license applications (BLA’s) in lieu of full reports. Applicants have experienced difficulties in the past in deciding when a full study report is required by the reviewing body. For example, clinical drug and biologic product development programs often include numerous clinical studies and resulting data that are not intended to contribute to the evaluation of the effectiveness of a product for a particular use and are not needed to support information included in labeling. Accordingly, such studies may be submitted as abbreviated reports or synopses, and this guidance is intended to facilitate their submission. This guidance is intended to provide guidance on the types of studies that may be submitted in abbreviated reports or synopses. The guidance also provides recommendations on the formats that should be used.

In the **Federal Register** of September 21, 1998 (63 FR 50241), FDA announced that it was submitting to the Office of Management and Budget (OMB) for review and clearance under the

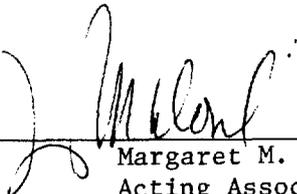
Paperwork Reduction Act of 1995 (PRA) the collection of information entitled “Application for FDA Approval to Market a New Drug—21 CFR Part 314—(OMB Control Number 0910–0001).” In that notice, FDA stated that the draft guidance entitled “Submission of Abbreviated Reports and Synopses in Support of Marketing Applications” (a notice announcing the availability of the draft guidance was published in the same issue of the **Federal Register**) would reduce the industry burden for submitting marketing applications under § 314.56 (21 CFR 314.50). FDA estimated that this reduction in burden would be approximately 300 hours, and reduced the industry burden estimate for § 314.50 accordingly. The **Federal Register** notice also requested comments on the burden estimates for part 314 (21 CFR part 314). OMB received no comments on the notice and approved the information collection for part 314 until November 30, 2001. In addition, none of the comments received in response to the notice announcing the availability of the draft guidance pertained to information collection issues under the PRA.

This guidance represents the agency’s current thinking on submission of full study reports, abbreviated reports, and synopses of information related to effectiveness for new drugs and biological products. 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, regulations, or both.

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals

may submit one copy. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/19/99
August 19, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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