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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-5333]

**Plans to Develop Guidance on Submitting an Archival Copy of an ANDA in Electronic Format; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration's (FDA's) Office of Generic Drugs (OGD), within its Center for Drug Evaluation and Research, is announcing plans to develop guidance on submitting an archival copy of a complete abbreviated new drug application (ANDA) in electronic format. OGD has encouraged the electronic submission of some types of data on a voluntary basis since 1997. However, these submissions are not archivable and are made in addition to a complete paper submission. OGD plans to expand its electronic data submission program to include all parts of the ANDA, so that the archivable electronic submission can replace the paper submission as the ANDA of record. OGD is soliciting comments from the public on its current program so it can consider these comments as it develops guidance for industry on the submission of complete, archivable ANDA's in electronic format. A draft guidance will be developed and made available for public comment. The ANDA electronic submission guidance will be one in a series of guidances the agency is developing to enable sponsors to submit archivable regulatory submissions in electronic format.

**DATES:** Submit written comments by [*insert date 60 days after date of publication in the Federal Register*]. General comments are welcome at any time.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the guidance

describing OGD's current program entitled "Preparing Data for Electronic Submission of ANDA's" are available on the Internet at <http://www.fda.gov/cder/guidance/index.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. Send one self-addressed adhesive label to assist that office in processing your requests. Additional information can be found on the Internet at <http://www.fda.gov/cder/OGD>.

**FOR FURTHER INFORMATION CONTACT:** Jonathan D. Cook, Center for Drug Evaluation and Research (HFA-358), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5683.

**SUPPLEMENTARY INFORMATION:** As part of the Prescription Drug User Fee Act, as amended by the Food and Drug Administration Modernization Act of 1997, the agency stated its plans to develop and update its information management capabilities to allow electronic submissions by 2002. In the **Federal Register** of January 28, 1999 (63 FR 4433 and 4432), the agency announced the availability of two guidances for industry entitled "Providing Regulatory Submissions in Electronic Format—General Considerations" and "Providing Regulatory Submissions in Electronic Format—NDA's." These guidances are the first in a series of guidances for industry on submitting archivable regulatory submissions in electronic format. In the 1999 guidance on general considerations, the agency stated that guidance would be forthcoming on other submission types, including investigational new drug applications, ANDA's, and product licensing applications. As part of that effort, OGD is announcing plans to develop guidance on submitting an archival copy of an ANDA in electronic format. As soon as a draft guidance has been developed, it will be made available for public comment.

OGD has accepted submission of some types of electronic data in ANDA's since 1997. During 1998, OGD received 32 electronic submissions for bioequivalence data and 44 electronic submissions for chemistry, manufacturing, and control data representing 58 distinct ANDA's from 24 different companies. The OGD program has been voluntary with the paper submission serving

as the archivable regulatory basis for review decisions. OGD plans to expand its electronic data submission program to include all parts of the ANDA, so that the archivable electronic submission can replace the paper submission as the ANDA of record.

Submission of an ANDA in electronic format is expected to yield many benefits to industry and FDA, including a more consistent submission, a more consistent and rapid review, and, in the future, reduction in archiving and storage space.

Electronic data files described in existing agency guidance and in more detail on the OGD program's Internet site will form the basis for paperless ANDA submissions. ANDA information not contained in the structured data submission (e.g., narratives and graphics) will be submitted in Portable Document Format (PDF), consistent with agency policy recommendations about filing PDF text and other files explained in the 1999 general considerations guidance.

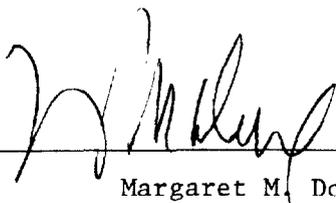
Pending completion of OGD's guidance on submitting archivable ANDA's in electronic format and in the absence of archiving capability, a complete paper ANDA submission is still required.

FDA is seeking input from interested parties on its current program for submitting electronic data to OGD. The agency would like to consider the public's comments as it develops guidance for industry on electronic submission of archivable ANDA's. A guidance for industry entitled "Preparing Data for Electronic Submission of ANDA's" describes OGD's current program.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the agency's current program and plans to develop guidance for industry on submitting complete, archivable ANDA's in electronic format. Two copies of any comments 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997), which provides for early public participation in the guidance development process.

Dated: 1/11/00  
January 11, 2000



Margaret M. Dotzel  
Acting Associate Commissioner for Policy

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