

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0364]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Annual Reports for New Drug Applications and Abbreviated New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Annual Reports for NDAs and ANDAs.” This draft guidance is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. The draft guidance discusses issues related to the electronic submission of annual reports for approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs) to FDA’s Center for Drug Evaluation and Research (CDER). It is expected that the submission of these reports in electronic format will improve the agency’s efficiency in processing, archiving, and reviewing the reports.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the **Federal Register***]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Randy Levin, Center for Drug Evaluation and Research (HFD-001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5411, e-mail: levinr@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Annual Reports for NDAs and ANDAs.” The draft document provides guidance to industry regarding submission of annual reports in electronic format for approved NDAs and ANDAs. This draft guidance is consistent with the forthcoming guidance being developed on the submission of annual reports based on the Electronic Common Technical Document.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on providing annual reports for approved NDAs and ANDAs in electronic format. 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.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comment on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection on respondents, including

through the use of automated collection techniques and other forms of information technology, when appropriate.

Title: Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Annual Reports for NDAs and ANDAs.

Description: FDA is issuing a draft guidance for industry on the electronic submission of annual reports for approved NDAs and ANDAs. The guidance is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. It is expected that the submission of these reports in electronic format will improve the agency's efficiency in processing, archiving, and reviewing the reports.

Sections 314.70(d), 314.81(b)(2), and 314.98 of FDA regulations (21 CFR 314.70(d), 314.81(b)(2), and 314.98) provide reporting requirements for submitting annual reports for approved NDAs and ANDAs. Section 314.81(b)(2) and FDA Form 2252 (Transmittal of Periodic Reports for Drugs for Human Use) specify the information required in the submission of annual reports. The submission of annual reports under these regulations, including FDA Form 2252, is approved by OMB until March 31, 2005, under OMB control number 0910–0001. The draft guidance states that this information, currently required to be submitted on paper, may be submitted in electronic format as described in the draft guidance.

The draft guidance also requests information that is not specifically required in the regulations and is not approved by OMB under control number 0910–0001. Section 314.81(b)(2)(iv) requires that chemistry, manufacturing, and controls (CMC) changes be submitted in the annual report. To facilitate the review of this information, the draft guidance requests that applicants provide in electronic format a current list of approved CMC information to

better document the changes occurring in applications. This information is currently requested in paper format in the guidance for industry entitled “Format and Content for the CMC Section of an Annual Report” (September, 1994) (see sections I and IV of part IV. Format and also attachment 1 of the guidance). The draft guidance requests that the list of approved CMC information include all information shown in attachment 1 of the September 1994 guidance, including: (1) The type and date of each change to each component; (2) the type of submission used to report the change (original, supplemental, or annual report); and (3) the date the change was reported and approved, if applicable.

Description of Respondents: Applicants that are required to submit annual reports updating information in an approved NDA or ANDA.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for the submission of the current list of approved CMC information. Based on the number of annual reports received for approved NDAs and ANDAs in calendar year 2002, FDA estimates that approximately 2,589 annual reports will be submitted by approximately 295 applicants for approved NDAs, and approximately 4,991 annual reports will be submitted by approximately 240 applicants for approved ANDAs. FDA estimates that it will take an applicant approximately 1 hour to prepare and attach the list of approved CMC information as requested in the draft guidance.

FDA invites comments on this analysis of information collection burdens.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

	No. of Respondents	Annual of Responses per Respondent	Total Responses	Hours per Response	Total Hours
NDAs	295	9	2,589	1	2,589
ANDAs	240	21	4,991	1	4,991
Total Hours					7,580

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To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to *fyokata@omb.eop.gov* or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Desk Officer for FDA, FAX: 202-395-6974.

IV. Electronic Access

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

Dated: August 20, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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