

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0033]

DUB

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Certifier	Romone Oliver

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format, Prescription Drug Advertising and Promotional Labeling; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling." The draft guidance discusses how to submit promotional materials in electronic format to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). This draft guidance is one of a series of guidances being developed by the agency to assist applicants who wish to make regulatory submissions in electronic format. Although submissions in electronic format are voluntary, the agency encourages them as a way to improve the efficiency of handling and reviewing documents and data.

DATES: Submit written comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*].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ADDRESSES: Copies of this draft guidance are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/guidelines.htm>. Written requests for copies of the draft guidance should be submitted to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane,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 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: 1-888-CBERFAX or 301-827-3844. Send one self-addressed adhesive label to assist the office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Warren F. Rumble, Center for Drug Evaluation and Research (HFD-001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2831, Rumblew@cder.fda.gov. or

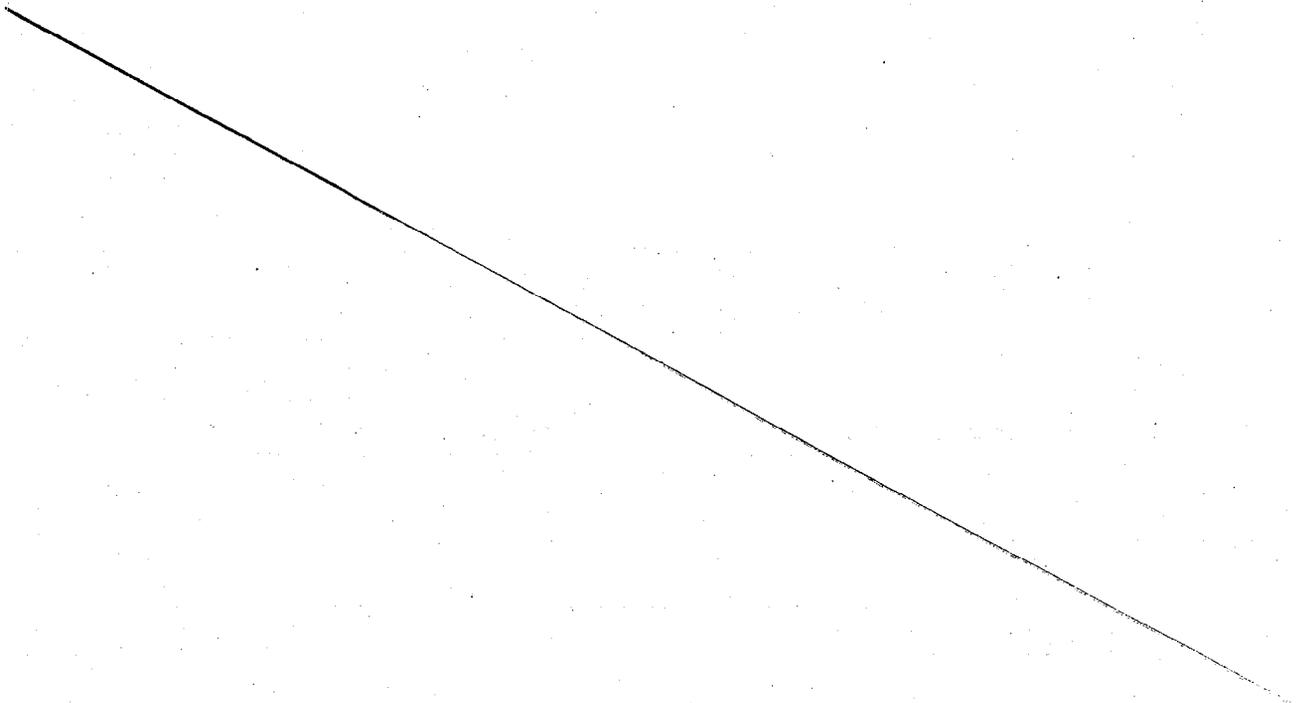
Michael B. Fauntleroy, Center for Biologic Evaluation and Research (HFM-99), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5101, esubprep@cber.fda.gov.

SUPPLEMENTARY INFORMATION: Traditionally, regulations have required that submissions, such as investigational new drug applications (IND's) and new drug applications (NDA's), be submitted as paper documents. In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records and electronic signatures regulation, which provided for the voluntary submission of parts or all of an application, as defined in the relevant regulations, in electronic format without an accompanying paper copy (21 CFR part 11). The agency also established public Docket No. 92S-0251 to provide a list of the agency unit(s) that are prepared to receive electronic submissions and the specific types of records and submissions that can be accepted in electronic format (62 FR 13467, March 20, 1997).

In the **Federal Register** of January 28, 1999 (64 FR 4433), CDER and CBER jointly published a guidance entitled "Providing Regulatory Submissions in Electronic Format—General Considerations." Since that time, CDER and CBER have included NDA's and BLA's on the docket as submission types that we are able to accept in electronic format.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance represents the agency's current thinking on providing promotional materials in electronic format to 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, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. As in the past, applicants planning to make submissions in electronic format should consult public Docket No. 92S-0251 to determine which agency units are prepared to receive electronic submissions and the specific types of documents that can be submitted in electronic format.



Dated: January 24 2001
January 24, 2001.

Ann M. Witt

Ann M. Witt,
Acting Associate Commissioner for Policy.

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