DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0148]

Open Meeting on World Health Organization Recommendations on Ephedrine and Other Substances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting concerning recommendations by the World Health Organization (WHO) to impose international manufacturing and distributing restrictions, under international treaties, on ephedrine and other drug substances. The comments received as a result of this public meeting will be considered in preparing the U.S. position on these proposals for a meeting of the United Nations Commission on Narcotic Drugs (CND) in Vienna, Austria, on March 16 through 25, 1999.

DATES: The public meeting will be held on Friday, February 19, 1999, from 9:30 a.m. to 4 p.m. Notifications on participation and/or attendance should be submitted by Tuesday, February 16, 1999.

ADDRESSES: The public meeting will be held in Parklawn Bldg., conference room C, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nicholas P. Reuter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1696, e-mail ''nreuter@oc.fda.gov''.

There is no registration fee, however, space is limited. Participants and persons interested in attending the public meeting should call the contact person listed in this document to register. Registrations also may be transmitted by fax to 1–301–443–0232. Please include the name and title of the person participating or attending, the name of the organization, telephone number, and fax number. An agenda and other information will be compiled after February 16, 1999.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 11, 1999 (64 FR 1629), FDA published a notice announcing the WHO recommendations to control substances under international drug control treaties. The notice also provided interested persons with the opportunity to submit written comments and to request an informal public meeting. In response to that notice, FDA received requests for a public meeting. The comments received as a part of this public meeting, along with information submitted in response to the January 11, 1999, notice will be considered in preparing the U.S. position on these proposals for a meeting of the CND in Vienna, Austria, on March 16 through 25, 1999.

Dated: January 22, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–2058 Filed 1–27–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0054]

Guidance for Industry on Providing Regulatory Submissions in Electronic Format—NDA's; 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 ''Providing Regulatory Submissions in Electronic Format—NDA's.'' The guidance discusses in detail how to submit a new drug application (NDA) in electronic format to the Center for Drug Evaluation and Research (CDER). A notice of availability for a related guidance entitled ''Providing Regulatory Submissions in Electronic Format—General Considerations'' is being published elsewhere in this issue of the **Federal Register**. It discusses issues common to all submissions in electronic format to CDER and the Center for Biologics Evaluation and Research (CBER). Both guidances are part of a series of guidances being developed by the agency to assist applicants who wish to make regulatory submissions in electronic format. Guidances addressing other submission types, such as biologics license applications, abbreviated new drug applications (ANDA's), and investigational new drug applications (IND's), are being developed and will be issued in the future. 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: Written comments on agency guidance documents may be submitted at any time.

ADDRESSES: Copies of this guidance for industry can be obtained 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. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this notice.

FOR FURTHER INFORMATION CONTACT: Kenneth Edmunds, Center for Drug Evaluation and Research (HFD–73), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3276, e-mail: ESUB@CDER.fda.gov.

SUPPLEMENTARY INFORMATION: Traditionally, FDA has required that regulatory submissions, such as IND's and 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). Shortly after establishing the docket, CDER published a guidance for industry entitled ''Archiving Submissions in Electronic Format—NDA's'' (62 FR 49695, September 23, 1997), to assist applicants wishing to make electronic submissions. The September 1997 guidance provided specific information on submitting case report forms (CRF's) and case report tabulations (CRT's) as part of the NDA archival submission.

In the **Federal Register** of April 8, 1998 (63 FR 17184), CDER published a draft guidance entitled ''Providing Regulatory Submissions in Electronic Format—NDA's''. This draft guidance expanded on the September 1997 guidance and provided new information

on submitting a complete archival copy of the NDA in electronic format, including CRF's and CRT's. The comment period, which closed on June 8, 1998, was extended 30 days to allow interested parties to review CDER's document together with guidances on electronic submissions published by CBER (63 FR 29741, June 1, 1998). The agency considered received comments as it finalized this guidance. Because of the ever changing nature of this technology, the agency believes that the procedures for submitting electronic applications will continue to evolve over time. To facilitate the updating of guidances on electronic submissions in a timely and efficient manner, the agency has decided to develop one guidance on those topics common to all submission types and to create individual guidances on specific submission types.

Subsequent guidances on other submission types will be issued as they are developed. Consistent with the agency's Good Guidance Practices (62 FR 8961, February 27, 1997), guidances will be issued first in draft for comment, then revised and published in final.

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.

This guidance document represents the agency's current thinking on providing NDA's in electronic format to CDER. 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 statute, regulations, or both.

Interested persons may submit written comments to the Dockets Management Branch (address above). 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 guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 22, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–2060 Filed 1–27–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0075]

Guidance for Industry on General Considerations for Providing Regulatory Submissions in Electronic Format; 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 ''Providing Regulatory Submissions in Electronic Format—General Considerations.'' This guidance discusses issues common to all submissions in electronic format to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). A notice of availability for a related guidance entitled ''Providing Regulatory Submissions in Electronic Format—NDA's'' is being published elsewhere in this issue of the **Federal Register**. Both guidances are part of a series of guidances being developed by the agency to assist applicants who wish to make regulatory submissions in electronic format. Guidances addressing other submission types, such as biologics license applications, abbreviated new drug applications (ANDA's), and investigational new drug applications (IND's), are being developed and will be issued in the future. 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: Written comments may be submitted at any time.

ADDRESSES: Copies of ''Guidance for Providing Regulatory Submissions in Electronic Format—General Considerations'' can be obtained 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 to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 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–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenneth Edmunds, Center for Drug Evaluation and Research (HFD–73), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3276, e-mail: ESUB@CDER.fda.gov; or Michael B. Fauntleroy, Center for Biologics Evaluation and Research, Office of the Director, (HFM–99), Food and Drug Administration, rm. 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–5101, e-mail: Esubprep@cber.fda.gov.

SUPPLEMENTARY INFORMATION: Traditionally, FDA has required that regulatory submissions, such as 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). Shortly after establishing the docket, CDER published a guidance for industry entitled ''Archiving Submissions in Electronic Format—NDA's'' (62 FR 49695, September 23, 1997), to assist applicants wishing to make electronic submissions. The September 1997 guidance provided specific information on submitting case report forms (CRF's) and case report tabulations (CRT's) as part of the NDA archival submission.

In the **Federal Register** of April 8, 1998 (63 FR 17184), CDER published a draft guidance entitled ''Providing Regulatory Submissions in Electronic Format—NDA's''; this draft guidance expanded on the September 1997 guidance and provided new information on submitting a complete archival copy of the NDA in electronic format, including CRF's and CRT's. In June 1998, CBER published four guidances on electronic submissions: (1) ''Electronic Submissions of a Biologics License Application (BLA) Product License Application (PLA)/ Establishment License Application