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

(ELA) to the Center for Biologics Evaluation and Research'' (63 FR 29741, June 1, 1998); (2) ''Electronic Submissions of Case Report Forms (CRF's), Case Report Tabulations (CRT's), and Data to the Center for Biologics Evaluation and Research'' (63 FR 29739, June 1, 1998); (3) ''Pilot Program for Electronic Investigational New Drug Applications (eIND) for Biological Products'' (63 FR 29740, June 1, 1998); and (4) ''Instructions for Submitting Lot Release Protocols to the Center for Biologics Evaluation and Research'' (63 FR 29742, June 1, 1998).

As part of agency efforts to harmonize the procedures for making electronic submissions, FDA has decided to combine certain information from the CDER and CBER guidances into this guidance on general considerations common to all submission types. The agency has considered received comments on the CDER and CBER guidances as it finalized this guidance document. Because of the ever changing nature of electronic submission technology and the need, for now, to recognize existing differences in CDER and CBER systems, the agency has decided to maintain separate guidances on CDER's NDA submissions and CBER's marketing application submissions. The agency will harmonize the concepts in the guidances to the extent our electronic systems permit.

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 issued in final. This final guidance incorporates information from the earlier draft CDER and CBER documents and takes into account comments received on them.

As in the past, applicants planning to make submissions in the 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 general considerations for providing regulatory submissions 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 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 the 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1266]

Draft Guidance for Industry on Placing the Therapeutic Equivalence Code on Prescription Drug Labels and 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 ''Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling.'' The draft guidance is intended to clarify for prescription drug manufacturers, relabelers, and distributors FDA's position regarding placing the therapeutic equivalence code on approved FDA product labels and labeling. It also provides recommendations on how to display therapeutic equivalence codes on labels and labeling. Inclusion of a therapeutic equivalence code on prescription drug labels/labeling is voluntary.

DATES: Written comments may be submitted by March 29, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft 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 draft 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 document.

FOR FURTHER INFORMATION CONTACT: Jerry Phillips, Center for Drug Evaluation and Research (HFD–610), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3225.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Placing the Therapeutic Equivalence Code on Prescription Drug Labels and Labeling.'' With the repeal of section 301(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(l)) as part of the Food and Drug Administration Modernization Act of 1997, FDA believes that it is legally permissible to allow therapeutic equivalence codes to be placed on drug product labels and labeling. The agency also believes that the use of therapeutic equivalence codes will contribute to the accurate and safe selection of generic products by pharmacists. This draft guidance is intended to: (1) Provide a historical perspective on therapeutic equivalence, (2) describe the process by which the agency advises the public on the therapeutic equivalence of approved drug products, and (3) advise manufacturers, relabelers, and distributors of the preferred format and placement of such information on product labels. Although inclusion of a therapeutic equivalence code on prescription drug labels/labeling normally is voluntary, in certain cases where safety issues are raised, the agency may ask that a code be included.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on placing the therapeutic equivalence code on the labeling of prescription drug 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 statute, regulations, or both.

Interested persons may, on or before March 29, 1999, 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 are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the