ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Office of Drug Evaluation IV (ODE IV), Center for Drug Evaluation and Research (CDER), is announcing the availability of several draft guidance documents on the development of antimicrobial drug products. A general draft guidance document entitled ''Developing Antimicrobial Drugs—General Considerations for Clinical Trials'' discusses issues common to the development of all antimicrobial drugs. The companion draft guidance documents address issues related to developing drugs to treat individual indications. These draft guidance documents are intended to help sponsors design clinical trials that will yield information the agency can use to determine whether the antimicrobial drug under study is safe and effective in the treatment of the specific infection studied. Key elements of these draft guidance documents will be discussed at a July 29, 30, and 31, 1998, Anti–Infective Drugs Advisory Committee meeting.

DATES: Written comments on the draft guidance documents may be submitted by October 27, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance documents are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance documents to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD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 Submit written comments on the draft guidance documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Renata Albrecht, Center for Drug Evaluation and Research (HFD–590), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2336.

SUPPLEMENTARY INFORMATION: FDA's divisions of Anti–Infective Drug Products, Special Pathogens and Immunologic Drug Products, and Anti–Viral Drug Products in CDER's ODE IV are issuing the first documents in a series of draft guidance documents that are intended to assist sponsors in designing, carrying out, and analyzing the results of clinical trials for the development of antimicrobial drug products. A general draft guidance document entitled ''Developing Antimicrobial Drugs—General Considerations for Clinical Trials'' discusses issues common to all antimicrobial drugs. The companion draft guidance documents address issues related to developing drugs to treat individual indications. Key elements from these draft guidance documents and related issues will be discussed at an Anti–Infective Drugs Advisory Committee meeting on July 29, 30, and 31, 1998 (63 FR 34655, June 25, 1998).

In the **Federal Register** of July 21, 1998 (63 FR 39096), ODE IV announced its plans for revising existing guidance documents and preparing new guidance documents on the development of antimicrobial drug products for the treatment of infections. ODE IV is reviewing, updating, consolidating, and revising its existing guidance documents and identifying topics for future guidance documents. In that notice, ODE IV explained its plan and requested public comment on topics for future guidance document development. The draft guidance documents are a part of ODE IV's guidance development plan.

The general draft guidance document being made available is entitled ''Developing Antimicrobial Drugs—General Considerations for Clinical Trials.'' The draft companion guidances are being made available on individual indications as follows:

- Uncomplicated urinary tract infections,
- Uncomplicated and complicated skin and skin structure infections,
- Community-acquired pneumonia,
- Nosocomial pneumonia,
- Acute bacterial exacerbation of chronic bronchitis,
- Secondary bacterial infection of acute bronchitis,
- Acute otitis media,
- Acute uncomplicated gonorrhea,
- Acute sinusitus,
- Complicated urinary tract infections and pyelonephritis,
- Bacterial prostatitis,
- Early Lyme disease,
- Empiric therapy of febrile neutropenia,
- Vulvovaginal candidiasis,
- Streptococcal pharyngitis and tonsillitis,
- Bacterial meningitis, and
- Bacterial vaginosis.

Additional guidances are under development.

The information in these draft guidance documents represents the agency's current thinking on developing antimicrobial 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 submit written comments on the draft guidance documents to the Dockets Management Branch (address above). 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 documents and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 23, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20239 Filed 7–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0448]

Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.'' The guidance document provides information on the electrocution hazard posed by unprotected patient electrical connectors. This guidance is intended to help affected parties understand the steps needed to achieve compliance with the performance standard for electrode lead wires and patient cables.

DATES: Written comments concerning this guidance must be received by October 27, 1998.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance entitled ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables'' to the Division of Small Manufacturers

Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Steward Crumpler, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–4659.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled'' Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.'' This guidance document addresses the implementation of the Performance Standard for Electrode Lead Wires and Patient Cables. This standard was issued to address the electrocution hazard posed by unprotected patient electrical connectors. Since May 11, 1998, electrode lead wires or patient cables intended for use with any of the following devices have been required to comply with the standard:

1. Breathing frequency monitors,
2. Ventilatory effort monitors (Apnea detectors),
3. Electrocardiographs (ECG's),
4. Radio frequency physiological signal transmitters and receivers,
5. Cardiac monitors,
6. Electrocardiograph electrodes (including pre-wired ECG electrodes),
7. Patient transducer and electrode cables (including connectors),
8. Medical magnetic tape recorders (e.g. Holter monitors),
9. Arrhythmia detectors and alarms,
10. Telephone Electrocardiograph transmitters and receivers.

Manufacturers and users have an additional 2 years to prepare for the second phase of implementation of the standard. Beginning on May 9, 2000, any electrode lead wire or patient cable lead intended for use with any medical device must comply with the standard.

The performance standard incorporates the specific requirements of international standard, IEC–60601, clause 56.3(c), which requires leads to be constructed in such a manner as to preclude patient contact with hazardous voltages or, for certain devices, contact with electrical ground. Design changes and labeling changes need to be considered by manufacturers and importers of the devices referenced previously.

Adapters can be used to convert devices already in the marketplace so they can accept electrode wires and patient cables that comply with the new performance standard.

This guidance document represents the agency's current thinking on the performance standard for electrode lead wires and patient cables. 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 applicable statute, regulations, or both. The agency has adopted good guidance practices (GGP's) (62 FR 8961, February 27, 1997), which set forth the agency's policy for the development, issuance and use of guidance documents. This is a Level 1 guidance document in accordance with the GGP's. The guidance document was made available on the World Wide Web (WWW) in March 1998 in order to provide guidance before the May 11, 1998, effective date of the first phase of implementation. Due to the risk of serious injury or death associated with the use of unprotected electrode leads and patient cables, this guidance is being implemented while the agency receives public input.

II. Comments

Interested persons may, on or before October 27, 1998, submit to the Dockets Management Branch (address above) written comments regarding this guidance document. 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 guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

In order to receive the ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1197) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the WWW. The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes the ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://ww.fda.gov/cdrh''.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

Dated: July 17, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3009–N]

RIN 0938–AI99

Medicare Program; Peer Review Organization Contracts: Solicitation of Statements of Interest From In-State Organizations—Alaska, Delaware, the District of Columbia, Hawaii, Idaho, Illinois, Kentucky, Maine, Nebraska, Nevada, South Carolina, Vermont, and Wyoming

AGENCY: Health Care Financing Administration, HHS.

ACTION: Notice.