experience with the use of the 3500A for mandatory medical device reporting and the need to collect information found only on the baseline report led the agency in 1998 to propose a major modification to the medical device sections of the 3500A form.

Dated: April 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–10616 Filed 4–25–03; 11:16 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0158]

Specification for Annotated Electrocardiographic Waveform Data in Electronic Format; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on proposed specifications for annotated electrocardiographic (ECG) waveform data in electronic format. The proposed specifications are described in a Health Level Seven (HL7) informative document.

DATES: Submit written or electronic comments on the specifications by May 29, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the specifications are available on the Internet at http://www.hl7.org/V3AnnECG/index.htm. Submit written comments on the specifications to the 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.

FOR FURTHER INFORMATION CONTACT: Norman Stockbridge, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5329, or e-mail: *stockbridgen@cder.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA considers the results of ECG tests in evaluating the safety and efficacy of certain new drugs, biologics, and devices. Traditionally, FDA has reviewed only summary representations of ECG data for the analysis of the safety and efficacy of products. The agency is interested in improving the evaluation of specific drug induced cardiac toxicity by reviewing ECG waveform data with detailed, sponsor generated annotations from the full spectrum of ECG devices, including 12-lead standard ECG, holter monitors, and implanted devices. On November 19, 2001, FDA held a public meeting to collect information regarding the content and format of annotated ECG waveform data that could be submitted to the agency in support of product applications.

Following the meeting, the Regulated Clinical Research Information Management Technical Committee (RCRIM) in HL7[1], in association with the Clinical Data Interchange Standards Consortium (CDISC)[2], investigated the technology necessary for the submission and review of this ECG data. The RCRIM then developed a model electronic format for the transportation of digital ECG waveform data, including annotations in the data message. The specifications on this annotated ECG waveform data message are provided in a proposed HL7 informative document. The document can be found on the HL7 Web site at http://www.hl7.org/V3AnnECG/index.htm.

II. Comments

We are interested in comments on the use of the proposed HL7 electronic format in providing annotated waveform ECG data to FDA in support of submissions for regulated products. Specifically, does the proposed message capture the appropriate level of detail about ECGs for assessment? Are there additions needed to the proposed controlled terminology? What are the issues concerning the creation of the HL7 message?

After FDA reviews any such comments concerning the HL7 proposal, the agency intends to issue a draft guidance setting forth its recommended electronic format for the submission of digital ECG waveform data. In those instances when the agency requests that a regulated entity submit ECG data electronically concerning a product, the draft guidance would describe an appropriate electronic format for the submission. Interested parties would have an opportunity to submit comments on this recommended format in response to the draft guidance. FDA would consider any such comments before publishing a guidance.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the proposed specification. Two paper copies of any 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 proposed specifications and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the proposed specifications at http://www.hl7.org/V3AnnECG/index.htm.

Dated: April 21, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–10475 Filed 4–28–03; 8:45 am]

BILLING CODE 4160–01–S

[1]Founded in 1987, Health Level Seven, Inc., (HL7) (www.HL7.org), is a nonprofit, ANSI-Accredited Standards Developing Organization that provides standards for the exchange, management and integration of data that supports clinical patient care and the management, delivery and evaluation of healthcare services. Its 2,200 members represent over 400 corporate members, including 90 percent of the largest information systems vendors serving healthcare. HL7 international affiliates are active in Europe, Japan, Australia, Canada, New Zealand, and Southern Africa.

[2]CDISC, (www.cdisc.org), is an open, multidisciplinary, nonprofit organization committed to the development of worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HRSA–03–097 Fiscal Year 2003 Competitive Application Cycle for the Nurse Education, Practice and Retention Grant Program Grants for Career Ladder Programs (CARL)—CFDA 93.359

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications will be accepted for the Nurse Education, Practice and Retention Grant Program; Grants for Career Ladder Programs for Fiscal Year 2003.

Purpose: Grants will be awarded to eligible entities for programs—

(A) To promote career advancement for nursing personnel in a variety of training settings, cross training or specialty training among diverse