TABLE 2.—Continued

Item No.	Title of Standard	Reference No. and Date
D. Radiology		
142	Lasers and laser-related equipment—Test methods for laser beam widths, Divergence angles, and beam propagation ratios—Part 2: General astigmatic beams	ISO 11146–2: 2005
143	Lasers and laser-related equipment—Test methods for determination of the shape of a laser beam wavefront—Part 2: Shack-Hartmann sensors	ISO 15367–2: 2005
E. Sterility		
169	Standard Test Method for Measuring Package and Seal Integrity Using Helium as Tracer Gas	ASTM F2391–05
170	Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials	ASTM F2475–05
171	Chemical Indicators—Guidance on the selection, use, and interpretation of results	ANSI/AAMI/ISO 15882: 2003

IV. List of Recognized Standards

FDA maintains the agency's current list of FDA recognized consensus standards in a searchable database that may be accessed directly at FDA's Web site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm*. FDA will incorporate the modifications and minor revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To be properly considered such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

In order to receive ''Guidance on the Recognition and Use of Consensus Standards'' on your fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 321 followed by the pound sign. Follow the remaining voice prompts to complete your request.

You may also obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing ''Modifications to the List of Recognized Standards, Recognition List Number: 014'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/cdrh*.

You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' through the hyperlink at *http://www.fda.gov/cdrh/stdsprog.html*.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/cdrh/fedregin.html*.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 014. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: March 23, 2006

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–4695 Filed 3–30–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0128]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Orphan-Drug and Humanitarian Use Device Designation Requests and Related Submissions; 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—Orphan-Drug and Humanitarian Use Device Designation Requests and Related Submissions.'' This is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. This guidance discusses issues related to the electronic submission of orphan-drug and humanitarian use device (HUD) designation requests and related submissions to the Office of Orphan Products Development (OPD). The submission of these documents in electronic format should improve the agency's efficiency in processing, archiving, and reviewing them.

DATES: Submit written or electronic comments on the draft guidance by May 30, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Electronic Submissions Coordinator, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6A–55, 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 Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: James D. Bona, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Orphan-Drug and Humanitarian Use Device Designation Requests and Related Submissions.'' This draft document provides guidance to industry regarding submissions of designation requests and related submissions to OPD in electronic format. It describes the two methods by which submissions can be made electronically to OPD. The first is totally electronic through use of FDA's electronic submission gateway pathway and the second is directly to OPD through the use of physical media (e.g., CD–ROMs). Recommendations are described for the formatting and organization of these submissions. A listing of agency contacts for assistance is also provided.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on providing designation requests and related 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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 draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This notice contains no new collections of information. The information requested for designation requests and related submissions is already covered by the regulations for orphan-drugs under 21 CFR 316.20 and for HUDs under 21 CFR 814.102. This notice announces the availability of a guidance that provides applicants with an alternative mechanism for submitting designation requests and related submissions to the agency. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/orphan/esub/esub.htm* or at *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 24, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–4709 Filed 3–30–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques of other forms of information technology.

Proposed Project: Loan Information System Records for the DHHS and DHUD Hospital Mortgage Insurance, Guarantee, and Direct Loan Programs (OMB No. 0915–0174)—Extension

The Division of Facilities and Loans within the Health Resources and Services Administration monitors outstanding direct and guaranteed loans made under section 621 of Title VI and section 1601 of Title XVI of the Public Health Service Act, as well as loans insured under the section 242 Hospital Mortgage Insurance Program of the National Housing Act. These programs were designed to aid construction and modernization of health care facilities by increasing the access of facilities to