

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Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Orphan-Drug and Humanitarian Use Device Designation Requests and Related Submissions;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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Orphan-Drug and Humanitarian Use Device Designation Requests and Related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DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the **Federal Register***]. 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Electronic Submissions Coordinator, Office of Orphan Products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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Orphan-Drug and Humanitarian Use Device Designation Requests and Related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.

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