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Certified For	J. M. Oudisot

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2171]

Medical Devices; Draft Guidance for the Accountability Analysis for Clinical Studies for Ophthalmic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled, "Accountability Analysis for Clinical Studies for Ophthalmic Devices." This guidance is intended to provide general information about the analysis of accountability of subjects in clinical studies in ophthalmic device investigational device exemption applications and marketing applications and notifications. By providing a reference point for the reporting of accountability information, FDA hopes that terminology and methods of presentation can be standardized so that the agency and sponsors can more effectively analyze these data. This guidance is not final nor is it in effect at this time.

DATES: Written comments concerning this guidance must be submitted by (*insert date 90 days after date of publication in the Federal Register*).

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Accountability Analysis for Clinical Studies for Ophthalmic Devices" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist the office in processing your request, or fax your request to 301-443-

8818. Submit written comments on the document to the Dockets Management Branch, (HFA-305), Food and Drug Administration, rm 1061, 5630 Fishers Lane, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Donna R. Lochner, Center for Devices and Radiological Health (HFZ-463), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2053.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled “Accountability Analysis for Clinical Studies for Ophthalmic Devices.” This guidance document provides background information that FDA and the sponsor can use in preparing accountability analyses for subjects enrolled in clinical studies of ophthalmic devices. It provides definitions of common terminology used in describing accountability, considerations for presentation of a “lost to follow-up” analysis, and sample formats for presentation of accountability. FDA has noted that there is often a misunderstanding in the meaning of certain terms used to describe accountability, which can confuse the presentation of the accountability data. Further, sponsors have frequently requested that FDA provide them with sample formats for presentation of accountability data. This guidance document attempts to provide some clarity in these areas.

II. Significance of Guidance

This guidance document represents the agency’s current thinking on the accountability analysis for ophthalmic devices. 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), which set forth the agency’s policies and procedures for the development, issuance, and use of guidance documents (62 FR

8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled "Accountability Analysis for Clinical Studies for Ophthalmic Devices" 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 (1350) 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 World Wide Web (WWW). CDRH maintains an entry on the World Wide Web for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. Updated on a regular basis, the CDRH home page includes the draft guidance entitled "Accountability Analysis for Clinical Studies for Ophthalmic Devices," 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://www.fda.gov/cdrh>".

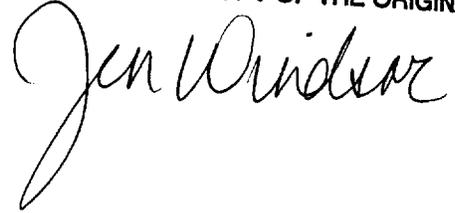
IV. Comments

Interested persons may, on or before (*insert date 90 days from date of publication in the Federal Register*), submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. 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. Comments should be identified with the docket number found in brackets in the heading of this document.

Dated: 7/20/99
July 20, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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