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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2075]

Global Harmonization Task Force; Draft Document on Proposal for Reporting of Use Errors with Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Global Harmonization Task Force (GHTF) draft document entitled "Proposal for Reporting of Use Errors with Medical Devices." The draft guidance includes information for regulatory authorities about reporting of adverse events that result in death or serious injury or certain types of near incidents. This draft document has been prepared by members of the GHTF Study Group 2 (SG2) on Medical Devices Vigilance/Postmarket Surveillance Reporting Systems. The draft document represents a harmonized proposal. Elements of the approach set forth in this draft document may not be consistent with current U.S. regulatory requirements. FDA is requesting comments on this draft document.

DATES: Written comments by (*insert date 30 days after date of publication in the Federal Register*). After the close of the comment period, written comments may be submitted at any time to Deborah Y. Blum (address below).

ADDRESSES: Submit written comments on the draft document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. If you do not have access to the World Wide Web (WWW), submit a written request for a 3.5" diskette of the draft document entitled "Proposal for Reporting of Use Errors with

Medical Devices” to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft document.

FOR FURTHER INFORMATION CONTACT: Deborah Y. Blum, Office of Surveillance and Biometrics (HFZ-520), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2985.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements, as described in an FDA notice on these activities published in the **Federal Register** of October 11, 1995 (60 FR 53078). As part of this effort, FDA has been actively involved since 1992 with GHTF. GHTF has formed four study groups, each tasked with assignments to draft documents and carry on other activities, designed to facilitate global harmonization. The purpose of this notice is to seek public comments on a draft document that has been prepared by one of the GHTF study groups.

SG2 was formed by GHTF in February 1996 and tasked with the responsibility to examine the requirements for the reporting of adverse incidents involving medical devices; consider postmarket surveillance and other forms of vigilance; and recommend ways of harmonizing these requirements. SG2 was also requested to promote the dissemination of relevant information concerning these matters. SG2 helps to improve protection of the health and safety to patients, users, and others; evaluate reports and disseminate information which may reduce the likelihood of or prevent repetitions of adverse events, or alleviate consequences of such repetitions; and define postmarket medical device reporting and surveillance requirements and guidelines on an international basis.

Reporting of adverse events involving medical devices is an important element in any good postmarketing surveillance system and can be achieved only through mutual confidence among all parties concerned. The obligation to report adverse events differs widely among countries. Some systems are voluntary, while others are mandatory. The common thread that could tie all of the worldwide reporting systems together is the obligation for manufacturers to report adverse events or incidents of which they are aware that involve medical devices.

It is the premise of the work of GHTF SG2 that an international system for reporting adverse events can be developed to handle information provided by the manufacturer to the authorities.

FDA is announcing the availability of a draft document entitled "Proposal for Reporting of Use Errors with Medical Devices." The GHTF SG2 has developed a reference for manufacturers regarding adverse event reporting. This draft document is referenced as SG2 N21R8 . It includes information for regulatory authorities about reporting of adverse events that result in death or serious injury or certain types of near incidents. It includes the consideration that certain types of failures may be exempt from reporting under regulatory vigilance procedures, but does not include a specific proposal on reporting of use errors. "Proposal for Reporting of Use Errors with Medical Devices" gives an overview on emerging process standards which are streamlining the handling of use errors by industry and makes a proposal to regulatory authorities on how to handle use errors under adverse event reporting procedures.

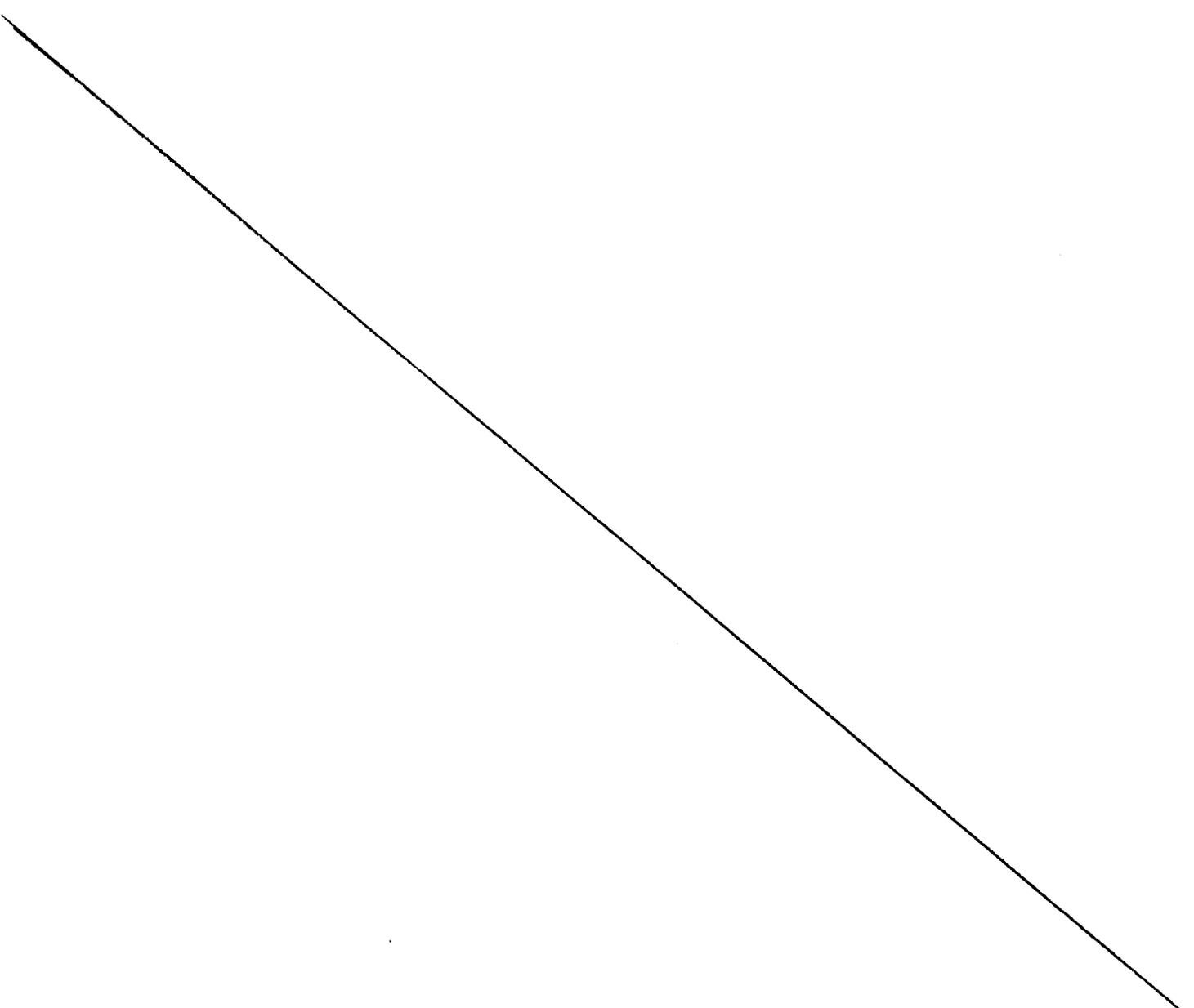
II. Electronic Access

Persons interested in obtaining a copy of the draft document may also do so using the WWW. 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 WWW. Updated on a regular basis, the CDRH home page includes the the draft document entitled "Proposal for Reporting of Use Errors with Medical Devices," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on videoconferencing and electronic

submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ‘<http://www.fda.gov/cdrh>’.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



After (*insert date 30 days after date of publication in the Federal Register*), written comments regarding the draft document may be submitted at any time to the contact person (address above).

Dated: 7/20/99
July 20, 1999

Linda S. Kahan

Linda S. Kahan
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Center for Devices and Radiological Health

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