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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2152]

Medical Devices; Device Use Safety: Incorporating Human Factors in Risk Management; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Draft Guidance on Device Use Safety: Incorporating Human Factors in Risk Management." This draft guidance is neither final nor is it in effect at this time. This draft guidance describes how to incorporate human factors techniques and theory into risk management during the development of medical devices. The draft guidance is intended to assist both reviewers of premarket device submissions and manufacturers that develop devices. The draft guidance is expected to decrease problems with the use of medical devices that impact safety and effectiveness and help ensure safer and more effective devices.

DATES: Written comments concerning this draft guidance must be submitted by (*insert date 90 days after date of publication in the Federal Register*).

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Draft Guidance on Device Use Safety: Incorporating Human Factors in Risk Management" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and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 request, or fax your request to 301-443-8818.

Submit written comments on the draft guidance to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ron D. Kaye, Center for Devices and Radiological Health (HFZ-230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3265.

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance provides a suggested approach for integrating human factors within risk management for medical device design and development. It also contains an introduction to both risk management and human factors and a discussion of how they are linked. The focus is on reducing risks related specifically to the use of medical devices. Human factors techniques are discussed in the context of management. The draft guidance also suggests how human factors-risk management efforts should be documented and included in premarket submissions.

This draft guidance document represents the agency's current thinking on applying human factors to new medical device design and development to help ensure that use of a device will be safe and effective. 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 draft guidance document is issued as a Level 1 guidance consistent with GGP's.

II. Electronic Access

In order to receive "Draft Guidance on Device Use Safety: Incorporating Human Factors in Risk Management" 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 (1497) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (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 "Draft Guidance on Device Use Safety: Incorporating Human Factors in Risk Management," 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>". The "Draft Guidance on Device Use Safety: Incorporating Human Factors in Risk Management" will be available at "<http://www.fda.gov/cdrh/HumanFactors.html>".

III. Comments

Interested persons may submit written comments regarding this draft guidance. Two copies of any comments are to be submitted to Dockets Management Branch (address above), 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 guidance and received

comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/20/99
July 20, 1999

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CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL
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