Center for Devices and Radiological, 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Submit written comments on the draft guidance to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Collin L. Figueroa, Center for Devices and Radiological Health (HFZ–341), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4654.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Draft Guidance on Quality System Regulation Information for Various PreMarket Submissions.'' This draft guidance document is intended to describe for manufacturers one means of complying with the requirements of the QS regulation in 21 CFR part 820 and the requirement for design controls and manufacturing information in various premarket submissions.

II. Significance of Guidance

When used by the premarket applicant in conjunction with the QS regulation, this draft guidance document illustrates an approach to comply with the content requirements for PMA and PDP submissions in section 515(c) of the Food, Drug, and Cosmetic Act (the act) (21 USC 360e(c)) and 21 CFR part 814. This document also describes the information that should be maintained at the manufacturing facility for premarket notifications submitted under section 510(k) of the act (21 U.S.C. 360(k)). The guidance document entitled ''The 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications'' (63 FR 25865, May 11, 1998) describes the type of design control information to be submitted in special 510(k)'s for device modifications.

This guidance document 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 This draft guidance document is issued as a Level 1 guidance consistent with GGPs.

III. Electronic Access

In order to receive the ''Draft Guidance Document on Quality System Regulation Information for Various PreMarket Submissions'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at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 (1140) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft document 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 ''Guidance on Quality System Regulation Information for Various PreMarket Submissions,'' 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 November 1, 1999, submit to the 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. Comments are to be identified with the docket number foundin 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: July 20, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–19869 Filed 8–2–99; 8:45 am]

BILLING CODE 4160–01–F

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 November 1, 1999.

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: July 20, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–19870 Filed 8–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3021–N]

Medicare Program; August 31, 1999 Open Town Hall Meeting To Discuss the End Stage Renal Disease Network Organizations (ESRD Networks) Activities

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting to provide an opportunity for health care organizations, beneficiary advocates, and other interested parties to offer comments and raise issues regarding the development of the ESRD Networks' contract activities to begin July 1, 2000. We view this new round of contracts as an opportunity to look at the current quality initiatives and how they might continue to improve the quality of care that our beneficiaries receive. The next Statement of Work will include Administration of the ESRD Program, beneficiary assistance (including grievances), quality improvement activities, and the collection of data to better understand and serve the ESRD population.

DATES: The meeting is scheduled for Tuesday, August 31, 1999 from 9 a.m. until 3 p.m., eastern daylight-saving time.

ADDRESSES: The meeting will be held in the Health Care Financing Administration Main Auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244.

FOR FURTHER INFORMATION CONTACT: Condict Martak, (410) 786–1366. Linda Okimoto, (410) 786–6877.

SUPPLEMENTARY INFORMATION:

Background

We contract with the End Stage Renal Disease Network Organizations (ESRD Networks) to oversee renal dialysis services furnished by dialysis facilities to Medicare beneficiaries. The ESRD Networks are responsible for ensuring beneficiaries receive quality care. Every 3 years we develop a Statement of Work defining the ESRD Networks' contract activities.

We are announcing a Town Hall meeting to provide an opportunity for organizations representing practitioners, providers, health plans, other purchasers, beneficiaries, and other interested parties to offer comments and raise issues regarding the activities that will be conducted by the ESRD Networks in their next contract beginning in July 2000. This Town Hall meeting provides an opportunity for the renal community to provide their comments directly to the HCFA officials responsible for writing and implementing the ESRD Network contracts.

Individuals who wish to make a short statement at the meeting must contact Condict Martak via e-mail at cmartak@hcfa.gov or Linda Okimoto via e-mail at lokimoto@hcfa.gov by close of business August 15, 1999. Also, because of time constraints, only a limited number of parties may be able to make presentations. We will notify participants who have been selected to make a presentation. We will assign presentation times and notify presenters before the meeting on August 31, 1999.

While the meeting is open to the public, attendance is limited to space available. Individuals must register in advance as described below or as described on the HCFA web site: http://www.hcfa.gov/quality/qlty-2.htm.

Registration

The Office of Clinical Standards and Quality will handle registration for the meeting. Registration forms may be obtained at HCFA's web site: http://www.hcfa.gov/quality/qtly-2.htm. Individuals may register by e-mail or by sending a FAX ((410) 786–4005) to the attention of Condict Martak or Linda