DATES: Written comments may be submitted at any time, however, comments should be submitted by October 4, 1999, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft ''Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics'' to the Office of Communication, Training, and Manufacturers Assistance (HFM0940), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852091448. Send one self-addressed adhesive label to assist the office in processing your request. The document may also be obtained by mail by calling the CBER Voice Information System at 10980009835094709 or 30109827091800, or by fax by calling the FAX Information System at 10988809CBER09FAX or 30109827093844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the document to the Dockets Management Branch (HFA09305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gloria J. Hicks, Center for Biologics Evaluation and Research (HFM0917), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852091448, 30109827096210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics.'' Once finalized, this document will supersede ''FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics,'' published in the **Federal Register** of November 25, 1992 (57 FR 55544). This revised guidance document is intended to advise current and potential manufacturers of biological and biotechnology products subject to licensure under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262) of available cooperative manufacturing arrangements. These arrangements include short supply, divided manufacturing, shared manufacturing, and contract manufacturing.

CBER recognizes that because development of important new biological products is both expensive and time consuming, increasing flexibility in manufacturing arrangements is desirable. In the **Federal Register** of May 14, 1996 (61 FR 24227), FDA published a final rule amending the biologics regulations at 21 CFR 601.2 to eliminate the establishment license application requirements for certain biotechnology and synthetic biological products subject to licensing under the PHS Act. This final rule also amended 21 CFR 600.3(t) to redefine the term ''manufacturer'' as it is used in 21 CFR 600 through 680. The definition was amended to include ''any legal person or entity who is an applicant for a license where the applicant assumes responsibility for compliance with the applicable product and establishment standards.'' This document is intended to provide guidance to those interested in the manufacture of new biological products, to those already engaged in cooperative manufacturing arrangements, and to those considering changing their present manufacturing arrangements. The guidance document may be useful to applicants submitting product, establishment, and biologics license applications and supplements.

This draft guidance represents the agency's current thinking on cooperative manufacturing arrangements for licensed biologics. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Written comments may be submitted at any time, however, comments should be submitted by October 4, 1999, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except 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 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.

III. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: July 27, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–19796 Filed 8–2–99; 8:45 am]

BILLING CODE 4160090109F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2212]

Medical Devices; Draft Guidance on Quality Systems Regulation Information for Various Premarket 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 entitled ''Guidance on Quality System Regulation Information for Various PreMarket Submissions.'' This draft guidance is intended to assist medical device manufacturers with information they should include in premarket approval applications (PMA) and product development protocols (PDP) to demonstrate that the submissions are in compliance with the revised quality system (QS) regulation. This draft guidance document also describes the information that should be maintained at the manufacturing facility for premarket notifications (510(k)'s). This draft guidance document represents the agency's current thinking on the QS regulation information for various premarket submissions. This guidance is neither final nor is it in effect at this time.

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 document entitled ''Draft Guidance on Quality System Regulation Information for Various PreMarket Submissions'' 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 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