DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2167]

Medical Devices; Draft Guidance on the Likelihood of Facilities Inspections When Modifying Devices Subject to Premarket Approval; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Draft Guidance on the Likelihood of Facilities Inspections When Modifying Devices Subject to Premarket Approval.'' The industry has experienced difficulties in planning the implementation of manufacturing and/or other changes involving a device with an approved premarket approval application (PMA), product development protocol (PDP), or humanitarian device exemption (HDE), when an FDA inspection may or may not be necessary. This draft guidance will help firms determine whether an FDA inspection is needed and more easily manage the timeframes associated with implementing changes in manufacturing while maintaining necessary safeguards. This guidance is not final nor is it in effect at this time.

DATES: Written comments concerning this draft guidance must be submitted by November 3, 1999.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5'' diskette of the guidance entitled ''Draft Guidance on the Likelihood of Facilities Inspections When Modifying Devices Subject to Premarket Approval'' to the Division of Small Manufacturers Assistance (HFZ–220),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 one self-addressed adhesive label 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Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Walter W. Morgenstern, Center for Devices and Radiological Health (HFZ–305), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4699.

SUPPLEMENTARY INFORMATION:

I. Background

During recent FDA/medical device industry grassroots forums, industry representatives discussed difficulties they have experienced in planning for changes related to devices with applications approved through the premarket approval (PMA), product development protocol (PDP) or humanitarian device exemption (HDE) processes. The industry representatives indicated that much of the difficulty was caused by uncertainty about FDA policies on what circumstances require submission of a PMA supplement, when a PMA inspection may be required, or when documenting the change in the firm's files may be adequate.

FDA, with input from interested parties, developed this draft guidance in an effort to help firms manage the timeframes associated with implementing changes in manufacturing facilities, manufacturing methods or procedures, labeling or performance.

This draft guidance identifies factors that are involved in determining the following: (1) Whether a change in manufacturing methods or procedures can be implemented and the device can be distributed without prior notice to FDA without any delay except that necessary to achieve compliance with the requirements of the Quality System/GMP regulation (21 CFR part 820); (2) whether a change in manufacturing methods or procedures can be implemented and the device can be distributed 30 days after prior written notice has been filed with FDA (30-Day Notice) in accordance with section 515(d)(6)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(6)(A)(i)) and 21 CFR 814.39, unless FDA notifies the holder of the PMA that the notice is inadequate; or (3) whether a change in facilities can be accelerated when a firm meets the prerequisite conditions for an Express PMA Supplement for Facilities Change.

The guidance is intended to reduce the regulatory burdens and concomitant delays in the implementation of a manufacturing change while maintaining necessary safeguards. The factors that an applicant and/or FDA should take into consideration when determining the need for submission of a supplement and the likelihood of an inspection are presented in a model decision procedure.

This draft guidance represents the agency's current thinking on changes to devices with approved PMA's, PDP's or HDE's. 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 requirements of the applicable statute, regulation, 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 document is issued as a Level 1 draft guidance consistent with GGP's.

II. Electronic Access

In order to receive the ''Draft Guidance on the Likelihood of Facilities Inspections When Modifying Devices Subject to Premarket Approval'' 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 the second voice prompt press 2, and then enter the document number (1269) 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 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 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''.

III. Comments

Interested persons may, on or before November 3, 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 found in brackets in the heading of this document. A copy of the draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 27, 1999

Linda S. Kahan,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N092075]

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 September 7, 1999. 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 (HFA09305), 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 (HFZ09220), 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 30109443098818. 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 (HFZ09520), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 30109594092985.

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

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