Dated: July 27, 1999

Linda S. Kahan,

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

[FR Doc. 99–20089 Filed 8–4–99; 8:45 am]

BILLING CODE 4160–01–F

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 The draft guidance includes information for regulatory authorities about reporting of adverse events that result in death or serious injury or certain types of near incidents.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

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 September 7, 1999, written comments regarding the draft document may be submitted at any time to the contact person (address above).

Dated: July 20, 1999.

Linda S. Kahan,

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

[FR Doc. 99–20140 Filed 8–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–205 & HCFA–R–206]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

ACTION: Comment request; notice.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

(1) *Type of Information Collection Request:* Revision of a currently approved collection;

Title of Information Collection: Information Collection Requirements Referenced in HIPAA for the Individual Market and Supporting Regulations in 45 CFR section 148;

Form No.: HCFA–R–205 (OMB# 0938–0703);

Use: These information collection requirements help ensure access to the individual insurance market for certain individuals and allows the States to implement their own program to meet the HIPAA requirements for access to the individual market. The information collection requirements outlined in this document are necessary for issuers and States to ensure individuals receive protection under section 111 of HIPAA.

Frequency: On occasion;

Affected Public: Business or other for-profit, Individuals or Households, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government;

Number of Respondents: 1,040;

Total Annual Responses: 3,230,000;

Total Annual Hours: 921,000.

(2) *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: Information Collection Requirements Referenced in HIPAA for the Group Market and Supporting Regulations in 45 CFR Section 146;

Form No.: HCFA–R–206 (OMB# 0938–0702);

Use: This regulation and related information collection requirements will ensure that group health plans provide individuals with documentation necessary to demonstrate prior creditable coverage, and the group health plans notify individuals of their special enrollment rights in the group health insurance market.

Frequency: On occasion;

Affected Public: Business or other for-profit, Individuals or Households, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government;

Number of Respondents: 2,030;

Total Annual Responses: 43,000,000;

Total Annual Hours: 2,700,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 29, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–20098 Filed 8–4–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–291]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

ACTION: Comment request; notice.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection;

Title of Information Collection: Multi-State Evaluation of Dual Eligibles Demonstrations: Wisconsin Partnership Program;

Form No.: HCFA–R–291 (OMB# 0938–NEW);

Use: This survey provides information needed to evaluate dual eligible demonstrations on issues of satisfaction and gathers health and functional status to be used in other analyses. Dual eligible demonstrations are designed to create alternative delivery services for acute and long-term care services to elderly and disabled persons which provide increased coordination, improve access to quality services and control or more appropriately allocate future costs. Respondents to the survey