Devices Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form'' provides guidance, procedures, and forms for the exchange of reports concerning the safety of medical devices between NCA and other participants of the GHTF National Competent Authority Report (NCAR) exchange program.

Study Group 4 was initially tasked with the responsibility of developing guidance documents on quality systems auditing practices. As a result of its efforts, this group has developed document SG4/N30R20:2006. SG4/N30R20:2006 (final document) entitled ''Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers—Part 2: Regulatory Auditing Strategy,'' which is intended to assist medical device regulators and organizations conducting quality management system audits to apply a process system approach to quality management system requirements (e.g. ISO 13485:2003 and 21 CFR part 820).

Study Group 5 was initially tasked with the responsibility of developing guidance documents on the content and documentation of clinical investigations. As a result of its efforts, this group has developed documents SG5(PD)N1R7:2006 and SG5(PD)N2R7.

SG5(PD)N1R7:2006 (proposed document) entitled ''Clinical Evidence—Key Definitions and Concepts'' introduces the concepts of clinical evaluation and clinical evidence, and examines the relationship between clinical investigation, clinical data, clinical evaluation, and clinical evidence. SG5(PD)N2R7:2006 (proposed document) entitled ''Clinical Evaluation'' provides guidance on how to conduct the clinical evaluation of a medical device as part of the conformity assessment procedure prior to placing a medical device on the market, as well as to support its ongoing marketing.

II. Significance of Guidance

These documents represent recommendations from the GHTF study groups and do not describe regulatory requirements. FDA is making these documents available so that industry and other members of the public may express their views and opinions.

III. Electronic Access

Persons interested in obtaining a copy of the guidances may also do so by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. Information on the GHTF may be accessed at *http://www.ghtf.org*. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding these documents. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 16, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–17727 Filed 10–23–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0353]

Draft Guidance for Industry and Food and Drug Administration Staff; Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems; 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 for Industry and FDA Staff: Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems.'' This draft guidance provides FDA's recommendations concerning portable invasive blood glucose monitoring systems (BGMSs).

DATES: Submit written or electronic comments on this draft guidance by January 22, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Draft Guidance for Industry and FDA Staff; Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems '' to the Division of Small Manufacturers, International, and Consumer 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 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Carol Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Road, Rockville, MD 20850, 240–276–0490 x117.

SUPPLEMENTARY INFORMATION:

I. Background

Portable invasive BGMS devices were introduced in the late 1970s and are considered one of the most important medical advances in diabetes care. This draft guidance document provides the FDA's recommendations concerning BGMS devices. In addition to recommendations for preparation of premarket notifications (510(k)), the draft guidance document discusses features of device design and risk management, including those relating to human factors. The draft guidance document, when finalized, is intended to complement International Standards Organization standards on risk management for medical devices and BGMSs. The scope of this draft guidance document includes BGMS devices, used in the quantitative measurement of glucose in blood by lay users at home or by professionals in hospitals and other point of care settings, to manage carbohydrate metabolism disorders including diabetes mellitus. When this guidance document is finalized, FDA expects that this guidance document will enable FDA to make more efficient and better-informed decisions based on more consistent data, and better contribute to the marketing of more

reliable, reproducible, and simple-to-use commercial devices.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the total product life cycle for portable invasive BGMSs. 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 and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Draft Guidance for Industry and FDA Staff; Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1603 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520). The collections of information in 21 CFR part 807 have been approved under OMB control number 0910–0120, the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073, and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 11, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–17757 Filed 10–23–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Office of Grants and Training, Citizens Corps; Agency Information Collection Activities: Submission for New Online Information Collection, Comment Request

AGENCY: Department of Homeland Security, Office of Grants and Training, Citizens Corps.

ACTION: Notice; 60-day notice request for comments.

SUMMARY: The Department of Homeland Security (DHS) invites the general public and other Federal agencies the opportunity to comment on new online information collection request 1670–NEW, Citizen Corps Profiles in Hometown Security Application 1670–NEW. As required by the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106), DHS is soliciting comments for the approved online information collection request.

DATES: Written comments should be received on or before December 26, 2006 to be assured consideration.

ADDRESSES: Citizen Corps, Attn: Jeanie Moore, 810 7th Street, NW., Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: Jeanie Moore, (202) 786–9858. This is not a toll free number.

SUPPLEMENTARY INFORMATION: Direct all written comments to the Department of Homeland Security at the above address. A copy of this Information Collection Request, with applicable supporting documentation, may be obtained by calling the Paperwork Reduction Act Contact listed above. The Office of Management and Budget is particularly interested in comments which:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Analysis

Agency: Department of Homeland Security, Office of Grants and Training, Citizens Corps.

Title: Citizen Corps Profiles in Hometown Security.

OMB No.: 1660–NEW.

Frequency: 1,430 times per year.

Affected Public: Citizen Corps Council Citizen Corps Council members, program managers, Program Partners and Affiliates.

Estimated Number of Respondents: 1,430 responses per year.

Estimated Time per Respondent: 2 hours per response.

Total Burden Hours: 2,860 hours.

Total Burden Cost: (capital/startup): None.

Total Burden Cost: (operating/maintaining): None.

Description: This online information collection available at *http://citizencorps.eyestreet.com/ccProfiles/secure/profileAdd.do?fromstart=fromstart* will enable Citizen Corps to operate effectively and efficiently. Profiles in Hometown Security will be a new online collection of 1-page summaries to communicate Citizen Corps members' involvement in safety and security incidents. By gathering this information and posting it to the Citizen Corps Web