Federal Register: Draft Guidance for Industry, Third Parties and Food and Drug Administration Staff; Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program; A...

U.S. Food & Drug Administration

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---------- DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration [Docket No. FDA-2010-D-0226] Draft Guidance for Industry, Third Parties and Food and Drug Administration Staff; Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program; Availability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---------- SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ``Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program.'' This draft guidance is intended to provide information on the implementation of a section of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which amends a section of the Federal Food, Drug, and Cosmetic Act (the act). This guidance document describes how FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) are implementing this provision of the law. This draft guidance is not final nor is it in effect at this time. DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by August 18, 2010. Submit written or electronic comments on the collection of information July 19, 2010. ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ``Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program'' to the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA), Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Room 4613, Silver Spring, MD 20993 or to the Office of Communications, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852- 1448. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. 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.regulations.gov [1]. Identify comments with the docket number found in brackets in the heading of this document. FOR

FURTHER INFORMATION CONTACT: Kimberly A. Trautman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Room 3422, Silver Spring, MD 20993, 301- 796-5515, or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210. SUPPLEMENTARY INFORMATION: I. Background This draft guidance is intended to provide information on the implementation of section 228 of FDAAA, which amends section 704(g)(7) of the act (21 U.S.C. 374(g)(7)). Under this draft guidance, device manufacturers whose establishment has been audited under one of the regulatory systems implemented by the Global Harmonization Task Force (GHTF) founding members1 using ISO 13485:2003 ``Medical devices-- Quality management systems--Requirements for regulatory purposes,'' may voluntarily submit the resulting audit report to FDA. If, based on that report, FDA determines there is minimal probability--in light of the relationship between the quality system deficiencies observed and the particular device and manufacturing processes involved--that the establishment will produce nonconforming and/or defective finished devices, then FDA intends to use the audit results as part of its risk assessment to determine whether that establishment can be removed from FDA's routine work plan for 1 year. The medical device ISO 13485:2003 Voluntary Audit Report Submission Program outlined in this draft guidance is another way in which FDA may leverage audits performed by other GHTF regulators and accredited third parties in order to assist the agency in setting risk-based inspectional priorities.

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1 The GHTF founding members auditing systems include the Canadian Medical Devices Conformity Assessment System; the European Union Notified Body accreditation system; the Therapeutics Goods Administration of Australia Inspectorate; and the Japanese Medical Device Ministry of Health, Labour and Welfare system.

This notice of availability and draft guidance satisfy the public notice requirement of section 704(g)(7)(F) of the act, which provides that FDA shall give public notice of the ISO standard(s) under which FDA accepts voluntary submissions of audit reports. 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 ``Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program.'' 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, Third Parties and FDA Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program'' you may either send an e-mail request to dsmica@fda.hhs.gov [2] to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1705 to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at http://www.fda.gov/cdrh/guidance.html [3]. Guidance documents are also available at http://www.regulations.gov [1] or at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm [4]. IV. Paperwork Reduction Act of 1995 Under the

Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501- 3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ``Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. Title: Draft Guidance for Industry, Third Parties and FDA Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program. Description: Section 228 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), amended section 704(g)(7) of the Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374(g)(7)) to add the following provision: ``(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality system standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with respect to the establishment during the preceding 2-year periods.'' The ``Draft Guidance for Industry, Third Parties and FDA Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program'' will describe how FDA's CDRH and CBER are implementing this provision of the law and providing public notice as required. The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements for implementing this voluntary submission program. FDA estimates the burden of this collection of information as follows: Table 1.--Estimated Annual Reporting Burden1

No. of Annual Frequency Total Annual Hours per Type of Respondent Respondents per Response Responses Response Total Hours

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Domestic or foreign 1,600 1 1,600 2 3,200 device manufacturer whose establishment was audited under ISO 13485:2003

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1 There are no capital costs or operating and maintenance costs associated with this collection of information. Based on FDA's experience with the founding regulatory members of GHTF, FDA expects that the vast majority of manufacturers who will participate in the Voluntary Audit Report Submission Program will be manufacturers who are certified by Health Canada under ISO 13485:2003.2 In 2008, approximately

2,650 manufacturers or manufacturing sites had been certified by Health Canada. ---------- 2 The majority of these manufacturers are also certified under ISO 13485:2003 by the European Union Notified Body accreditation system.
---------- In addition, FDA only expects firms who do not have major deficiencies or observations in their ISO 13485:2003 audits to be willing to submit their audit reports to FDA under the Voluntary Audit Report Submission Program. FDA analyzed its inspection data from Fiscal Year (FY) 2008 (October 1, 2007 to October 1, 2008) and determined that the total number of inspections finalized in FY2008 for medical devices was 1,965. The breakdown for the 1,965 compliance decisions is as follows: Table 2.--Compliance Decision Breakdown

Compliance Decision1	Number	Approximate Percentage
Official Action Indicated	148	8%
Voluntary Action Indicated	775	40%
No Action Indicated	1,025	52%
Pending Final Decision	17	1%

---------- 1 June 15, 2006, Compliance Program 7382.845 Inspection of Medical Device Manufacturers Part V http://www.fda.gov/cdrh/comp/guidance/7382.845.html#p5p5.pdf [5]. Because FDA only expects firms who do not have major deficiencies or observations to be willing to submit their audit reports to FDA under the Voluntary Audit Report Submission Program, FDA only expects to receive audit reports that would have been classified by FDA as No Action Indicated (NAI). Assuming that the percentage breakdown of compliance decisions for all inspections conducted in FY2008 can be extrapolated and applied to audits of manufacturers certified under ISO 13485:2003 by Health Canada, FDA can estimate the number of Canadian establishments that would have had an inspection classified as an NAI. Since 52 percent of all compliance decisions resulted in a NAI decision, FDA estimates that 1,378 of the facilities certified under ISO 13485:2003 by Health Canada (52 percent of the total 2,650 facilities) would have had an inspection classified as an NAI. Since FDA only expects to receive audit reports that would have been classified by FDA as NAI, FDA expects 1,378, or approximately 1,400, audit reports to be submitted. Since FDA expects that the vast majority of manufacturers who will participate in the Voluntary Audit Report Submission Program will be manufacturers certified by Health Canada under ISO 13485:2003, FDA expects the number of reports to be submitted from manufacturers certified by regulatory systems established by other founding GHTF members to be minimal. For purposes of calculating the reporting burden, FDA estimates that approximately 10 percent of total audit reports submitted under this program will be from these other manufacturers. Since 90 percent of the audit reports are expected to be submitted by manufacturers certified by Health Canada (approximately 1,400 audit reports as calculated previously in this document), then the total number of audit reports FDA expects to receive in a year is 1,556, or

approximately 1,600, audit reports. FDA further estimates that the gathering, scanning, and submission of the audit reports, certificates, and related correspondence would take approximately 2 hours. This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073 and the collections of information for the Inspection by Accredited Persons Program have been approved under OMB control number 0910-0569. 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 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: May 17, 2010. Leslie Kux, Acting Assistant Commissioner for Policy. [FR Doc. 2010-12098 Filed 5-19-10; 8:45 am] BILLING CODE 4160-01-S

SOURCE [6]

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http://www.mdtmag.com/news/2010/05/federal-register-draft-guidance-industry-third-parties-and-food-and-drug-administration-staff-medical-device-iso-134852003-voluntary-audit-report-submission-program

Links:
[1] http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.regulations.gov
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[5] http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/cdrh/comp/guidance/7382.845.html%23p5p5.pdf
[6] http://edocket.access.gpo.gov/2010/2010-12098.htm