beneficiaries with tools to better manage their diabetes and to achieve good clinical and behavioral outcomes. Based on the information submitted by the AADE, we believe that the AADE is striving to meet the same goals we developed for quality DSMT.

IV. Provisions of the Final Notice

AADE's application to continue as an accredited NAO to deem entities for the purposes of DSMT is approved for a period of 3 years. The accreditation is effective on August 27, 2012. This approval is subject to renewal subsequent to the receipt of an application from the AADE and subject to review, evaluation, and approval of its program.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare-Hospital Insurance Program; and No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: July 3, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–17293 Filed 7–26–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0630]

Draft Guidance for Industry and Food and Drug Administration Staff; Safety Considerations for 510(k) Submissions To Mitigate the Risks of Misconnections With Small-Bore Connectors Intended for Enteral Applications; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Safety Considerations for 510(k) Submissions to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications.'' The use of common connector designs, such as luer connectors, has led to unintended connections between devices that have different intended uses and has resulted in serious and sometimes fatal consequences to patients. This guidance provides recommendations to 510(k) submitters regarding the submission expectations regarding design and testing to reduce the risk of unintended connections between enteral and nonenteral devices. This draft guidance is not final nor is it in effect at this time.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 either electronic or written comments on the draft guidance by October 25, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Safety Considerations for 510(k) Submissions To Mitigate the Risks of Misconnections With Small-Bore Connectors Intended for Enteral Applications'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. 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 electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Priya Venkataraman-Rao, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G222, Silver Spring, MD 20993–0002, 301–796–6243.

I. Background

Multiple publications regarding patient injury and death from tubing and catheter misconnections indicate that reports of misconnections have gradually increased in frequency. On July 9, 2010, FDA issued a letter to health care professionals, hospital purchasing departments, and manufacturers of enteral feeding tubes regarding luer lock misconnections. FDA advised manufacturers to assess the risks of misconnections for their devices and provide proposed solutions with validation for premarket review. At that time, some manufacturers were using color coding and labeling to reduce the risk of misconnections; others were creating proprietary connectors designed to be incompatible with nonenteral devices. However, recent reports of adverse events have demonstrated that reliance on color-coding of enteral devices alone cannot adequately mitigate the risk of misconnections, especially with similarly color-coded PICC (percutaneously inserted central catheter) lines on the market.

This guidance provides updated recommendations to manufacturers on the submission requirements for 510(k)s for small-bore connectors used in enteral applications. The guidance recommends that 510(k) submitters (1) Design and test enteral connectors based on the Association for the Advancement of Medical Instrumentation (AAMI)/American National Standards Institute (ANSI)/International Organization for Standardization (ISO) 80369–1, ''Small-Bore Connectors for Liquids and Gases in Healthcare Applications—Part 1: General Requirements'' standard; (2) no longer rely strictly on color coding and tagging to prevent misconnections; and (3) perform risk assessments to demonstrate that the proposed design and testing has effectively mitigated the risk of the proposed enteral connector misconnecting to nonenteral 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 mitigating the risks of misconnections with small-bore connectors intended for enteral applications. 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. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To

receive ''Safety Considerations for 510(k) Submissions To Mitigate the Risks of Misconnections With Small-Bore Connectors Intended for Enteral Applications,'' you may either send an email request to *dsmica@fda.hhs.gov* 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 1784 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently 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 U.S.C. 3501–3520). The collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910–0130; the collections of information found in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

The labeling provisions of this draft guidance are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the recommended enteral connector labeling is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public.'' (see 5 CFR 1320.3(c)(2)).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments 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: July 23, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18332 Filed 7–26–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project Title: Healthy Weight Learning Collaborative Evaluation (OMB No. 0915–xxxx)—[New]

Background: Supported by the Prevention and Public Health Fund created by Section 4002 of the Affordable Care Act, HRSA awarded $5 million to the National Initiative for Children's Healthcare Quality (NICHQ) to create the Collaborate for Healthy Weight, a national initiative to bring together primary care providers, public health professionals, and leaders of community-based organizations to use quality improvement methods to address the obesity epidemic in communities across the country. A key part of that initiative was creation of the Healthy Weight Learning Collaborative (HWLC), a quality improvement project working with 50 community teams to identify, test, and evaluate a national ''change package'' of evidence-based program and policy interventions to address childhood obesity. The HWLC is being implemented in two consecutive phases, each with a series of learning sessions and action periods. The first phase (July 2011 to July 2012) includes 10 community teams; the second phase (March 2012 to March 2013) includes 40 additional teams.

Purpose: The purpose of this evaluation is to assess the quality and effectiveness of the HWLC. This 1-year information collection will supplement the analysis of existing quantitative HWLC administrative and team data by collecting primary data using individual and group interviews with two groups of stakeholders: (a) NICHQ project leadership, staff, and faculty; and (b) community team members at 11 selected sites (four Phase One teams and seven Phase Two teams). Data from these interviews will be used to evaluate the quality and effectiveness of the HWLC. NICHQ leadership, staff, and faculty interview topics include: The design and implementation of the HWLC project; the content and quality of the HWLC learning sessions, coaching assistance, and other action period activities; the community teams' experiences implementing the HWLC change package and quality improvement indicators; and stakeholders' perceptions of the quality and effectiveness of the HWLC in accelerating community efforts to address childhood obesity.

Community team interviews will be conducted with the team coordinator, the quality improvement data manager, and other team members, including primary care providers, public health officials, school administrators, and other community volunteers. Separate interview protocols will be developed for the Phase 1 and Phase 2 community teams. Phase 1 protocols will examine community team strategies, activities, and approaches that have been sustained and spread after the end of Phase 1. Phase 2 protocols will examine (1) Team goals, objectives, and program elements; (2) team implementation of the HWC change package; (3) team engagement in HWLC activities; and (4) team linkages and organizational and policy changes resulting from the team's participation in the HWLC.

Estimate of response burden is as follows: