4160-01-P

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Draft Guidance for Industry and Food and Drug Administration Staff; Safety Considerations for 510(k) Submissions to Mitigate the Risks of Misconnections With Small-Bore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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Safety Considerations for 510(k) Submissions to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications."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 This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Safety Considerations for 510(k) Submissions to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral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Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

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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 07/26/2012 at 8:45 am; Publication Date: 07/27/2012]