to assemble supporting scientific information when the claim is novel or when the claim is pre-existing but the scientific underpinnings of the claim are not widely established. These are claims that may be based on emerging science, where conducting literature searches and understanding the literature takes time. It is also possible that references for claims made for some dietary ingredients or dietary supplements may primarily be found in foreign journals and in foreign languages or in the older, classical literature where it is not available on computerized literature databases or in the major scientific reference databases, such as the National Library of Medicine's literature database, all of which increases the time of obtaining substantiation.

In the **Federal Register** of January 6, 2000 (65 FR 1000), we published a final rule on statements made for dietary supplements concerning the effect of the product on the structure or function of the body. In that final rule, we estimated that there were 29,000 dietary supplement products marketed in the United States (65 FR 1000 at 1045). Assuming that the flow of new products is 10 percent per year, then 2,900 new dietary supplement products will come on the market each year. The structure/function final rule estimated that about 69 percent of dietary supplements have a claim on their labels, most probably a structure/function claim (65 FR 1000 at 1046). Therefore, we assume that supplement manufacturers will need time to assemble the evidence to substantiate each of the 2,001 claims ($2{,}900 \times 69$ percent) made each year. If we assume that the 2,001 claims are equally likely to be pre-existing widely established claims, novel claims, or pre-existing claims that are not widely established, then we can expect 667 of each of these types of claims to be substantiated per year. Table 1 of this document shows that the annual burden hours associated with assembling evidence for claims is 189,428 (the sum of 667×44 hours, 667×120 hours, and 667×120 hours).

Dated: February 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02787 Filed 2–10–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0630]

Safety Considerations To Mitigate the Risks of Misconnections With Small-Bore Connectors Intended for Enteral Applications; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Safety Considerations 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 manufacturers regarding the expectations for design and testing of small-bore connectors intended for enteral applications (''enteral devices''). FDA is making these recommendations to reduce the risk of unintended connections between enteral and non-enteral devices.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Safety Considerations to Mitigate the Risks of Misconnections with Small-Bore Connectors Intended for Enteral Applications'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the 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.

SUPPLEMENTARY INFORMATION:

I. Background

Numerous publications regarding patient injury and death from tubing and catheter misconnections indicate that reports of misconnections have increased in frequency over the past several years. On July 9, 2010, FDA issued a letter to healthcare professionals, hospital purchasing departments, and manufacturers of enteral feeding tubes regarding Luer lock misconnections (Ref. 1). 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 devices for non-enteral applications (''non-enteral devices''). However, recent reports of adverse events have demonstrated that reliance on color-coding and tagging of enteral devices alone cannot adequately mitigate the risk of misconnections, especially with similarly color-coded intravenous PICC (percutaneously inserted central catheter) lines with Luer connectors.

This guidance provides updated recommendations to manufacturers of small-bore connectors intended for enteral applications. The guidance recommends that manufacturers: (1) Design and test enteral connectors based upon Association for the Advancement of Medical Instrumentation (AAMI)/CN3:2014 (PS), ''Small-bore connectors for liquids and gases in healthcare applications—Part 3: Connectors for enteral applications'' and AAMI/CN20:2014 (PS), ''Small-bore connectors for liquids and gases in healthcare applications—Part 20: Common test methods''; (2) for connectors that do not meet AAMI/CN3:2014 (PS), design and test connectors based upon the AAMI/American National Standards Institute (ANSI)/International Organization for Standardization (ISO) 80369–1 standard ''Small-bore connectors for liquids and gases in healthcare applications—Part 1:

General requirements''; (3) no longer rely solely on color-coding, labeling, and tagging to prevent misconnections; and (4) perform and document risk assessments to demonstrate that the proposed design and testing have effectively mitigated the risk of the enteral connector misconnecting to non-enteral devices.

Elsewhere in this issue of the **Federal Register**, we are announcing a publication containing modifications to the list of standards that FDA recognizes for use in premarket reviews (''FDA Recognized Consensus Standards''). Specifically, this publication announces the addition of a list of recognized standards that are relevant to safety considerations to mitigate the risks of misconnections with small-bore connectors intended for enteral applications. This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 039'' (''Recognition List Number: 039''), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices, specifically small-bore connectors for enteral applications.

In the **Federal Register** of July 27, 2012 (77 FR 44256), FDA announced the availability of the draft guidance document. We invited interested persons to comment by October 25, 2012. Seven sets of comments were received and offered strong support for the finalization of this guidance as part of a continued effort to reduce the likelihood of incidents involving unintended connections between connectors with different intended uses. Multiple comments also applauded FDA for collaborating with the standards organizations to address this issue.

The comments also noted the potential drawbacks of aligning the recommended testing with the current version of the AAMI/ANSI/ISO 80369–1 standard. Its methodologies, particularly those in Annex B, seek to demonstrate that each proposed enteral connector is physically incompatible with non-enteral devices. However, ISO is proposing substantial changes for future versions that could affect the recommended testing. FDA acknowledges this potential drawback; however, the current version of 80369–1 was the available reference at the time. As noted above, additional consensus standards relating to the design and testing of small-bore connectors intended for enteral applications have been published and recognized. Therefore, the guidance has been modified accordingly to reference and align with these recognized standards.

Multiple comments also suggested that the description of included and excluded devices be modified and clarified, and gave examples for consideration. The guidance has been modified accordingly. Several comments requested language and definition changes to provide more clarity and consistency with the published standard, which FDA has considered and incorporated as appropriate. Lastly, due primarily to space considerations on the label affixed to a device, multiple comments expressed concern regarding FDA's recommendation to eliminate the use of shortened terms such as ''enteral-only'' or ''non-IV'' in favor of more descriptive labeling. FDA has considered these comments and recommends that the device's instructions for use, as opposed to its affixed label, fully describe the subject connector's interconnectability. The instructions for use will afford adequate space for the recommended longer phrases describing the devices to which the subject connector can and cannot connect. However, for connectors for which non-interconnectability has been demonstrated, the product design could also incorporate color-coding, labeling, and tagging or imprinting on the connector.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Safety Considerations to Mitigate the Risks of Misconnections with Small-Bore Connectors Intended for Enteral Applications'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1784 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This 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 (the PRA) (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 guidance are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA. 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 either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at *http://www.regulations.gov.*

VI. References

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available

electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA Center for Devices and Radiological Health, Letters to Industry Page, ''Letter to Manufacturers of Enteral Feeding Tubes,'' (*http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM218631.pdf*).

Dated: February 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02802 Filed 2–10–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0288]

Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; 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 ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices.'' This leap frog guidance document was developed to notify manufacturers of the recommended non-clinical and clinical studies to support a premarket approval application (PMA) for implantable MIGS 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 of 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 May 12, 2015.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

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: Michelle Tarver, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 2504, Silver Spring, MD 20993–0002, 301–796–5620.

SUPPLEMENTARY INFORMATION:

I. Background

When finalized, this draft guidance document will recommend non-clinical and clinical studies to support a PMA for implantable MIGS devices. Glaucoma is a progressive condition that damages the optic nerve of the eye, is associated with elevated intraocular pressure, and leads to irreversible vision loss. It is the second leading cause of visual disability and blindness in the world, with 1 in 40 adults over 40 years of age suffering from glaucoma having some visual loss. Current surgical treatments are aimed at reducing intraocular pressure (IOP) and often reserved for moderate to severe disease. During the past decade, novel medical devices, called MIGS devices, have emerged. These devices are designed to treat less severe glaucoma by enhancing physiological aqueous outflow with an approach that causes minimal ocular trauma.

This draft guidance is a leap-frog guidance; leap frog guidances are intended to serve as a mechanism by which the Agency can share initial thoughts regarding the content of premarket submissions for emerging technologies and new clinical applications that are likely to be of public health importance very early in product development, generally before FDA has even received any such submissions. This leap-frog guidance represents the Agency's initial thinking and our recommendations may change as more information becomes available. The Agency strongly encourages manufacturers to engage with the Center for Devices and Radiological Health (CDRH) through the Pre-Submission process to obtain more detailed feedback for implantable MIGS devices. For more information on Pre-Submissions, please see ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' (*http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf*).

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 implantable MIGS devices. 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 downloading an electronic copy from 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.* Persons unable to download an electronic copy of ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400049 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

The guidance document ''Premarket Studies of Implantable Minimally Invasive Glaucoma Surgical (MIGS) Devices'' refers to previously approved information collections found in FDA regulations and guidance. 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 814, subparts B and E are approved under OMB control number 0910–0231 and the collections of information in the guidance document entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with