4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0435]

Surveying, Leveling, or Alignment Laser Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug administration (FDA) is announcing the availability of the draft guidance entitled "Surveying, Leveling, or Alignment Laser Products." This draft guidance, in question and answer format, is intended for manufacturers of laser products and outlines the FDA's proposed approach regarding the applicability of FDA's performance standard regulations to surveying, leveling, or alignment (SLA) laser products. SLA lasers are a subcategory of specific-purpose laser products that transmit laser radiation through open space for surveying, alignment, or leveling purposes. The draft guidance is not final nor is in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].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: 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 Submit written requests for a single hard copy of the draft guidance document entitled "Surveying, Leveling, or Alignment Laser Products" to the Office of the Center Director, Guidance and Policy Development, Center for Devices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. 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Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Robert J. Doyle, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4672, Silver Spring, MD 20993-0002, 301-796-5863.

I. Background

This draft guidance is intended to provide a brief summary of the FDA's proposed approach on the applicability of performance standards for laser products to specific purpose SLA laser products. An SLA laser product is defined in 21 CFR 1040.10(b)(39) as "a laser product manufactured, designed, intended or promoted for one or more of the following uses: (i) Determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement, (ii) positioning or adjusting parts in proper relation to one another, (iii) defining a plane, level, elevation, or straight line." The topics that are addressed include the definition of an SLA laser product, examples of SLA laser products, design features of SLA laser

products, the applicability of class limits to SLA laser products, and questions and answers relating to the application of FDA's performance standard regulations to SLA laser products.

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 surveying, leveling, or alignment laser products. 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 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.

To receive the "Surveying, Leveling, or Alignment Laser Products" draft guidance you may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1764 to identify the guidance you are requesting.

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 U.S.C. 3501-

3520). The collections of information in 21 CFR 1040.10 and 1040.11 have been approved under OMB control number 0910-0025.

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: April 30, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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