4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1045]

Medical Devices; Custom Devices; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration Safety and Innovation Act (FDASIA), which was signed into law on July 9, 2012, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The Food and Drug Administration (FDA) is in the process of developing an implementation strategy and policy for the custom device exemption criteria in the FD&C Act amended by FDASIA. FDA is seeking information on appropriate uses of the custom device exemption.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments 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.

FOR FURTHER INFORMATION CONTACT:

Bryan Benesch,

Center for Devices and Radiological Health,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 66, rm. 3424,

Silver Spring, MD 20993-0002,

301-796-5506.

SUPPLEMENTARY INFORMATION:

I. Background

Section 520(b) of the FD&C Act (21 U.S.C. 360j(b), as amended by section 617 of FDASIA (Public Law 112-144), sets forth the requirements that must be met in order for a device to qualify for a custom device exemption (Ref. 1). Section 520(b) of the FD&C Act exempts "custom devices" from performance standard or premarket approval requirements under sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e), if these devices meet the enumerated statutory requirements, including, among others, the following for each device: (1) is "created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing)"; (2) must not be "generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution"; (3) must be for the purpose of treating a "unique pathology or physiological condition that no other device is domestically available to treat"; and (4) must be manufactured for the "special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of the physician or dentist (or other specially qualified person so designated)" or by an individual patient named in such order.

In addition to these new requirements for establishing a custom device, manufacturers will have limitations for use of a custom device only for the purpose of treating a "sufficiently

rare condition, such that conducting clinical investigations on such device would be impracticable" and production of the device must be limited to no more than five units per year of a particular device type. Lastly, manufacturers will be required to submit an annual report explaining their use of the custom device exemption under section 617 of FDASIA.

FDA is seeking information on and examples of appropriate uses of the custom device exemption identified in section 520(b) of the FD&C Act. FDA encourages all stakeholders, including patients, physicians, dentists, and manufacturers, to submit comments on the appropriate use of this statutory provision.

FDA is particularly interested in receiving information relating to:

1. Input from patients, manufacturers, dentists, or physicians on where use of the custom device exemption is appropriate.
2. Specific instances where manufacturers, dentists, or physicians have used, would have liked to use, or plan to use the custom device exemption for treatment of a sufficiently rare condition.
3. Product areas other than orthopedic and dental devices where the custom device exemption may be useful.
4. The type of information manufacturers intend to require a physician, dentist, or other qualified person to submit to them when ordering a custom device.
5. How often a custom device is ordered due to unusual anatomical features of the individual physician/dentist, or due to a unique need in the physician's/dentist's practice not shared by health professionals of the same specialty (i.e., a special need of a physician or dentist).

This notice provides the first opportunity for the public to comment on these issues. The public will have a second opportunity to provide input when the Agency announces the availability of a draft guidance document and a draft regulation for implementing section 520(b) of the FD&C Act.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. 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.

III. Reference

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 are available electronically at http://www.regulations.gov.

1. The Food and Drug Administration Safety and Innovation Act, available at http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm20027187.htm.

Dated: November 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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