(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2015–0240, dated December 18, 2015; Rotax Aircraft Engines BRP Service Bulletin SB–912–066 R1/SB–914–047 R1 (published as one document), Revision 1, dated April 23, 2015; Diamond Aircraft Industries GmbH Optional Service Bulletin OSB 36–111, dated September 17, 2015; Diamond Aircraft Industries GmbH Work Instruction WI–OSB 36–111, dated September 17, 2015; Diamond Aircraft Service Bulletin No.: DA20–72–04, dated January 22, 2015; Diamond Aircraft Industries GmbH Optional Service Bulletin OSB 20–066, dated September 17, 2015; Diamond Aircraft Industries GmbH Work Instruction WI–OSB 20–066, dated September 17, 2015; and Scheibe Aircraft GmbH Service Information 02/14–1, dated December 15, 2014, for related information. You may examine the MCAI on the Internet at *https://www.regulations.gov/#!documentDetail;D=FAA-2016-4878-0002*. For information on the availability of the service documents above, contact the FAA, Small Airplane Directorate, at 816–329–4148.

(i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Rotax Aircraft Engines BRP Service Bulletin SB–912–068 and SB–914–049 (co-published as one document), dated April 16, 2015.

(ii) Reserved.

(3) For BRP-Powertrain GmbH & CO KG service information identified in this AD, contact BRP-Powertrain GmbH & Co. KG, Welser Strasse 32, A–4623 Gunskirchen, Austria; phone: +43 7246 601 0; fax: +43 7246 601 9130; Internet: *www.rotax-aircraft-engines.com*.

(4) You may view this service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. In addition, you can access this service information on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–4878.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued in Kansas City, Missouri, on June 1, 2016.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–13542 Filed 6–9–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2016–N–1308]

Medical Devices; Ophthalmic Devices; Classification of Nasolacrimal Compression Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the nasolacrimal compression device into class I (general controls). The Agency is classifying the device into class I (general controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective June 10, 2016. The classification was applicable on April 20, 2016.

FOR FURTHER INFORMATION CONTACT: Daniel Fedorko, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2414, Silver Spring, MD 20993–0002, 301–796–6620.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On June 27, 2014, Innovatex, Inc., submitted a request for classification of the Tear Duct Occluder (originally referred to as the Glaucoma Companion Nasolacrimal Compression Device) under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class I (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class I if general controls by themselves are sufficient to provide reasonable assurance of safety and effectiveness of the device for its intended use. After review of the information submitted in the de novo request, FDA determined that the device can be classified into class I. FDA believes general controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 20, 2016, FDA issued an order to the requestor classifying the device into class I. FDA

is codifying the classification of the device by adding 21 CFR 886.5838.

The device is assigned the generic name nasolacrimal compression device, and it is identified as a prescription device that is fitted to apply mechanical pressure to the nasal aspect of the orbital rim to reduce outflow through the nasolacrimal ducts.

The risks to health that may be associated with use of the nasolacrimal compression device are improper fit of the device (extended or aggressive use of this device may cause sequelae such as bruising and/or soreness) and improper use of the device (for the uncoordinated, a corneal abrasion may occur inadvertently). General controls of the FD&C Act, including compliance with the labeling requirements in 21 CFR part 801 and the Quality System Regulation (21 CFR part 820), are sufficient to mitigate these risks and reasonably assure safety and effectiveness. FDA believes that the general controls provide reasonable assurance of safety and effectiveness.

The nasolacrimal compression device is not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109, *Prescription devices*).

Section 510(l) of the FD&C Act provides that a class I device is not subject to the premarket notification requirements under section 510(k) of the FD&C Act, unless the device is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA has determined that the device does meet these criteria and, therefore, premarket notification is not required for the device. Thus, persons who intend to market this device need not submit a premarket notification containing information on the nasolacrimal compression device they intend to market prior to marketing the device, subject to the limitations on exemptions in 21 CFR 886.9.

II. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order refers to previously approved collections of information found in other 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 part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding the quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

IV. Reference

The following reference is on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *http://www.regulations.gov*.

1. DEN140022: De novo request from Innovatex, Inc., dated June 27, 2014.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

■ 1. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 886.5838 to subpart F to read as follows:

§ 886.5838 Nasolacrimal compression device.

(a) *Identification.* A nasolacrimal compression device is a prescription device that is fitted to apply mechanical pressure to the nasal aspect of the orbital rim to reduce outflow through the nasolacrimal ducts.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

Dated: June 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–13788 Filed 6–9–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2015–D–3539]

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' The guidance describes FDA's interim regulatory policy regarding outsourcing facilities that compound human drug products using bulk drug substances while FDA develops the list of bulk drug substances that can be used in compounding under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the