II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A–95–11) detailing the waiver process and discussing the information hospitals must provide in requesting a waiver. We indicated that upon receipt of a waiver request, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the comments received. During the review process, we may consult on an as-needed basis with the Health Resources and Services Administration's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver request and notify the hospital and the designated and requested OPOs.

III. Hospital Waiver Request

In accordance with § 486.308(e), the following hospital has requested a waiver to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located:

Carson Valley Medical Center, Gardnerville, Nevada, is requesting a waiver to work with: California Transplant Donor Network, 1000 Broadway, Suite 600, Oakland, California 94607–4099.

The Hospital's Designated OPO is: Nevada Donor Network, 2061 E. Sahara Ave., Las Vegas, Nevada 89104.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

V. Response to Public Comments

We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble.

Dated: May 2, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–10641 Filed 5–7–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1601]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Custom Device Exemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 9, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Custom Device Exemption''. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Custom Device Exemption—(OMB Control Number 0910–NEW)

I. Background

The custom device exemption is set forth at section 520(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(b)(2)(B)). A custom device is in a narrow category of device that, by virtue of the rarity of the patient's medical condition or physician's special need the device is designed to treat, it would be impractical for the device to comply with premarket review regulations and performance standards.

Effective July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) implemented changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended the existing custom device exemption and introduced new concepts and procedures for custom devices, such as:

- Devices created or modified in order to comply with the order of an individual physician or dentist;
- the potential for multiple units of a device type (limited to no more than five units per year) qualifying for the custom device exemption; and
- annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed under section 520(b) of the FD&C Act.

Under FDASIA, ''devices'' that qualify for the custom device exemption contained in section 520(b) of the FD&C Act were clarified to include no more than ''five units per year of a particular device type'' that otherwise meet all the requirements necessary to qualify for the custom device exemption.

The guidance also provides draft definitions of terms used in the custom device exemption, explains how FDA plans to interpret the concept of ''five units per year of a particular device type'' in section 520(b)(2)(B) of the FD&C Act, describes what information manufacturers should submit in a custom device annual report (annual report) to FDA, and provides guidance on how to submit an annual report for devices distributed under the custom device exemption.

On November 19, 2012, FDA published a notice requesting comments in the **Federal Register** (77 FR 69488), requesting that stakeholders submit information on and examples of appropriate use of the custom device exemption for assistance in drafting this guidance based on specific questions asked in the notice. FDA has reviewed all the comments from the notice and has taken them into consideration for this draft guidance.

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 the custom device exemption. 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.html.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Custom Device Exemption,'' 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 1820 to identify the guidance you are requesting.

Draft Guidance for Custom Device Exemption

This guidance is intended to assist industry by providing draft definitions of terms used in the custom device exemption, to explain how FDA proposes to interpret the ''five units per year of a particular device type'' language contained in section 520(b)(2)(B) of the FD&C Act, to describe what information FDA proposes that should be submitted in a custom device annual report, and to provide recommendations on how to submit an annual report for devices distributed under the custom device exemption. In addition, manufacturers of custom devices are required to sign and submit a Custom Devices Annual Report Truthful and Accurate certificate with their annual report.

Description of Respondents: The respondents of this collection of information are manufacturers of medical devices deemed to be custom devices subject to FDA's laws and regulations.

In the **Federal Register** of January 14, 2014 (79 FR 2446), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance Title: Custom Device Exemption	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Section VI. Annual Reporting	33	1	33	40	1,320

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates it will receive 33 reports for custom devices annually. The Agency reached this estimate by the number of pre-FDASIA manufacturers who qualified for custom devices and that percentage of current manufacturers that qualify under post-FDASIA requirements. Only 10 percent of manufacturers would meet this qualification, which was calculated by adding the number of estimated old custom device manufacturers with the estimated new manufacturers submitting annual reports of custom devices each year. FDA estimates it will take custom device manufacturers approximately 40 hours to complete the annual report described in section VI of the draft guidance. FDA reached this time estimate based on its expectation of the amount of information that should be included in the report.

Before the proposed information collection provisions contained in this draft guidance become effective, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814, subparts B and E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120.

Dated: May 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–10579 Filed 5–7–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0052]

Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a draft guidance for industry entitled ''Draft Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications.'' The draft guidance, when finalized, will explain our current thinking on the preparation of regulatory submissions for obtaining exemptions for ingredients from the labeling requirements for major food allergens in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) through submission of either a petition or a notification.

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 we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 5, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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. All comments should be identified with the