

- 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.

In the **Federal Register** of September 24, 2014 (79 FR 57112), FDA announced the availability of the guidance entitled “Custom Device Exemption.” FDA has developed this document to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in the FD&C Act. The intent of the guidance is to define terms used in the custom device exemption, explain how to interpret the “five units per year of a particular device type” language contained in the FD&C Act, describe information that FDA proposes

manufacturers should submit in the custom device annual report, and provide recommendations on how to submit an annual report for devices distributed under the custom device exemption.

In the **Federal Register** of March 21, 2017 (82 FR 14518), 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 <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual reporting for custom devices .....	33	1	33	40	1,320

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 20, 2017.

**Anna K. Abram,**  
Deputy Commissioner for Policy, Planning,  
Legislation, and Analysis.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2017–N–3331]

**Arthritis Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Arthritis Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA’s regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on August 2, 2017, from 8 a.m. to 5 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Answers to commonly asked questions including information regarding special

accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2017–N–3331. The docket will close on August 1, 2017. Submit either electronic or written comments on this public meeting by August 1, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 1, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of August 1, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before July 19, 2017, will be provided to the committee.

Comments received after that date will be taken into consideration by the Agency.

You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://>

[www.regulations.gov](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 <https://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 manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA–2017–N–3331 for “Arthritis Advisory Committee; Notice of Meeting;

Establishment of a Public Docket; Request for Comments.” Received comments, those filed in a timely manner (see **ADDRESSES**) will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: [AAC@fda.hhs.gov](mailto:AAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the

Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* The committee will discuss biologics license application (BLA) 761057, for sirukumab injection (proposed trade name PLIVENSIA), submitted by Janssen Biotech, Inc., for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to one or more disease modifying anti-rheumatic drugs. The discussion will include dose selection, efficacy, radiographic progression study, and safety.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions must be submitted on or before August 1, 2017. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 11, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably

accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 12, 2017.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Philip Bautista at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 20, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Low-Income Levels Used for Various Health Professions and Nursing Programs Authorized in Titles III, VII, and VIII of the Public Health Service Act

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** HRSA is updating income levels used to identify a “low-income family” for the purpose of determining eligibility for programs that provide health professions and nursing training to individuals from disadvantaged backgrounds. These various programs are authorized in Titles III, VII, and VIII of the Public Health Service Act.

HHS periodically publishes in the **Federal Register** low-income levels to be used by institutions receiving federal grants and cooperative agreements to