Date and Time: The meeting will be held on November 5, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person for More Information: Caleb Briggs, 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: *ODAC@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 *http://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.

Agenda: During the morning session, there will be a presentation and general discussion of the potential applicability of pharmacological and cellular manipulation of the immune system, as a potential therapeutic intervention in various pediatric cancers. The recent, dramatic results of inhibition of the PD–1/PD–L1 axis and checkpoint inhibitors on normal T cells in melanoma and other adult cancers strongly suggest a potential role for such agents in the management of childhood cancer. Information will be presented regarding pediatric development plans for two products that are in late stage development for various adult oncology indications. The subcommittee will consider and discuss issues relating to the development of each product for potential pediatric use and provide guidance to facilitate the formulation of Written Requests for pediatric studies, if appropriate. The two products under consideration are: (1) Nivolumab, application submitted by Bristol-Myers Squibb Co. and (2) MK–3475, application submitted by Merck Sharp & Dohme.

During the afternoon session, information will be presented regarding pediatric development plans for LEE011, application submitted by Novartis Pharmaceuticals Corp., a product in early-stage development for adult and pediatric oncology indications. The subcommittee will consider and discuss issues relating to the development of this product for possible pediatric use and provide guidance to facilitate the formulation of Written Requests for pediatric studies, if appropriate.

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 *http://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 subcommittee. Written submissions may be made to the contact person on or before October 30, 2013. Oral presentations from the public will be scheduled between approximately 10:15 a.m. to 10:45 a.m., and 1:20 p.m. to 1:50 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 October 28, 2013. 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 October 29, 2013.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caleb Briggs 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 *http://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: October 10, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–24798 Filed 10–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Ear, Nose and Throat Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ear, Nose and Throat Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 8, 2013, from 8 a.m. to 6 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

For those unable to attend in person, the meeting will also be Webcast. The Webcast will be available at the following link: *https://collaboration.fda.gov/entdevices.*

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993, 301–796–5290, *Natasha.Facey@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 *http://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.

Agenda: On November 8, 2013, the committee will discuss, make recommendations, and vote on information regarding the premarket approval (PMA) application for the Nucleus® Hybrid™ L24 Implant System sponsored by Cochlear Americas. The proposed Indications for Use for the Nucleus® Hybrid™ L24 Implant System (as stated in the PMA) is as follows:

The Nucleus® Hybrid™ L24 Implant System is intended for patients aged 18 years and older who have residual low-frequency hearing sensitivity and bilateral severe to profound high frequency sensorineural hearing loss, and who obtain limited benefit from bilateral hearing aids.

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 *http://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. Written submissions may be made to the contact person on or before October 31, 2013. 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 October 22, 2013. 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 October 24, 2013.

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 physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at *AnnMarie.Williams@fda.hhs.gov* or 301–796–5966 at least 7 days in advance of the meeting. Requests for sign language interpretation or Communication Access Realtime Translation (CART)/captioning must be made 2 weeks in advance of the meeting, no later than October 25, 2013.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://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: October 18, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–24832 Filed 10–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1137]

GlaxoSmithKline LLC; Withdrawal of Approval of the Indication for Treatment of Patients With Relapsed or Refractory, Low Grade, Follicular, or Transformed CD20 Positive Non-Hodgkin's Lymphoma Who Have Not Received Prior Rituximab; BEXXAR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the indication for treatment of patients with relapsed or refractory, low grade, follicular, or transformed CD20 positive non-Hodgkin's lymphoma who have not received prior rituximab, for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection held by GlaxoSmithKline LLP, P.O. Box 5089, 1250 South Collegeville Rd., Collegeville, PA 19426 (Glaxo). Glaxo has voluntarily requested that approval of this indication be withdrawn and has waived its opportunity for a hearing.

DATES: Effective October 23, 2013.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: FDA approved BEXXAR on June 27, 2003, for the treatment of patients with CD20 positive, relapsed or refractory, low-grade, follicular, or transformed non-Hodgkin's lymphoma who have progressed during or after rituximab therapy. On December 22, 2004, FDA approved a new indication to include patients who have not received prior rituximab (the rituximab-naïve indication) under the Agency's accelerated approval regulations for biological products, 21 CFR part 601, subpart E.

On December 13, 2011, FDA requested that Glaxo voluntarily withdraw the rituximab-naïve indication for BEXXAR (tositumomab and iodine I 131 tositumomab) Injection because the postmarketing study intended to verify clinical benefit and required as a condition of approval under part 601, subpart E was not completed. Withdrawal of approval of the rituximab-naïve indication does not otherwise affect the approved indication for BEXXAR.