Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (January through March 2016)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, there were no specific updates that have occurred to the list of Medicare-approved facilities that meet our standards in the 3-month period. This information is available at *http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage.* For questions or additional information, contact Marie Casey, BSN, MPH (410–786–7861).

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (January through March 2016)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commision on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no updates to the listing of facilities for lung volume reduction surgery published in the 3-month period. This information is available at *www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage.* For questions or additional information, contact Marie Casey, BSN, MPH (410–786–7861).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (January through March 2016)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at *www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage.* For questions or additional information, contact Sarah Fulton, MPH (410–786–2749).

Addendum XV: FDG–PET for Dementia and Neurodegenerative Diseases Clinical Trials (January through March 2016)

There were no FDG–PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our Web site at *www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage.* For questions or additional information, contact Stuart Caplan, RN, MAS (410–786–8564).

[FR Doc. 2016–10819 Filed 5–6–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–4602]

Streamlining Regulations for Good Manufacturing Practices for Hearing Aids; Public Workshop; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the document entitled ''Streamlining Regulations for Good Manufacturing Practices for Hearing Aids; Public Workshop'' that appeared in the **Federal Register** of January 7, 2016. In the document, FDA requested comments on the appropriate level of good manufacturing practices (GMPs) regulation to ensure the safety and effectiveness of air-conduction hearing aid devices. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published January 7, 2016 (81 FR 784). Submit either electronic or written comments by June 30, 2016.

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 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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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–2015–N–4602 for ''Streamlining Regulations for Good Manufacturing Practices for Hearing Aids; Public Workshop; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Srinivas Nandkumar, Food and Drug Administration, Center for Devices and Radiological Health, Bldg. 66, Rm. 2436, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6480, FAX: 301–847–8126, *Srinivas.nandkumar@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 7, 2016 (81 FR 784), FDA published a document with a 30-day comment period to request comments on the appropriate level of GMPs regulation to ensure the safety and effectiveness of air-conduction hearing aid devices; the current regulations for air-conduction hearing aids that may hinder innovation, reduce competition, and lead to increased cost and reduced use of these devices by Americans with age-related hearing loss; and the potential exemption of hearing aids from the Quality System Regulation (QSReg,) through use of alternative standards developed in collaboration with key stakeholders and standards development organizations, and recognized by FDA and recordkeeping to ensure product quality. Comments on the ''Streamlining Regulations for Good Manufacturing Practices for Hearing Aids'' will inform the Agency on an alternative model for quality verification.

The Agency has received requests for a 30-day extension of the comment period for the document. Each request conveyed concern that the current 30-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the document on ''Streamlining Regulations for Good Manufacturing Practices for Hearing Aids.''

FDA has considered the requests and is extending the comment period for the document on ''Streamlining Regulations for Good Manufacturing Practices for Hearing Aids'' for 30 days, until June 30, 2016. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying regulation on these important issues.

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10798 Filed 5–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Advisory Committee; Anesthetic and Analgesic Drug Products Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Anesthetic and Analgesic Drug Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Anesthetic and Analgesic Drug Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until May 1, 2018.

DATES: Authority for the Anesthetic and Analgesic Drug Products Advisory Committee will expire on May 1, 2016, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Stephanie L. Begansky, 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, *AADPAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Issued in 41 CFR 102–3.65 and approval by the Department of Health and Human Services issued in 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Anesthetic and Analgesic Drug Products Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Anesthetic and Analgesic Drug Products Advisory Committee advises the Commissioner or designee in discharging responsibilities