



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Ms. Karyl D. Haskell
Vice President, Clinical and Regulatory Affairs
NeuroVasx, Inc.
7351 Kirkwood Lane N., Suite 112
Maple Grove, MN 55369

APR 1 2011

Re: H100002
HUD 09-0218
cPAX Aneurysm Treatment System
Filed: April 27, 2010
Amended: July 6 and September 29, 2010, and January 5, 2011
Product Code: OUU (Polymeric Neurovascular Embolization Device)

Dear Ms. Haskell:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your humanitarian device exemption (HDE) application for the cPAX Aneurysm Treatment System. This device is indicated for use in the adult population (22 years of age and older) for the treatment of wide-necked large and giant sized cerebral aneurysms > 10 mm that require use of adjunctive assist-devices such as stents or balloons. CDRH is pleased to inform you that your HDE is approved subject to the enclosed "Conditions of Approval." You may begin commercial distribution of the device upon receipt of this letter.

In addition to the postapproval requirements in the enclosure, the postapproval reports must include the following information:

As a condition of approval, you must conduct the following post-approval study and submit annual PAS report bearing the applicable HDE reference number to the address below.

New Enrollment Study: Per the protocol outline submitted by email dated February 25, 2011, the study will be a prospective, multi-center, non-randomized, unblinded assessment of the cPAX Aneurysm Treatment System for the treatment of wide-necked intracranial aneurysms, which are > 10 mm and which require the use of adjunct assist devices such as stents or balloons. The study will be conducted at five sites in the United States. The primary study objective is the rate of aneurysms, which have stable occlusion, in the absence of a post-treatment re-bleed of the treated aneurysm, at 1 year follow up. Stable occlusion will be defined by the Modified Raymond Scale. As agreed on e-mail dated March 30, 2011, patients 22 years old and older will be included in the PAS. A total of 122 subjects will be enrolled to obtain 103 subjects followed for 1 year. Study follow-up visits include: Immediate post treatment, 48 hours post treatment, Hospital Discharge, 90 day follow up, 6 month follow up, and 1 year follow up.

The data analysis of the primary performance endpoint will include an analysis of those aneurysms which were a 1 or a 2 at treatment. The primary performance endpoint is the proportion of aneurysms that are stable in the absence of a post-treatment re-bleed. The primary safety endpoint will be the rate of device-related hydrocephalus, aseptic meningitis or other inflammatory response through 12 months.

In addition, up to 15 cPAX training subjects will be reported on separately. Training subjects will be required for the investigators who have not yet used the cPAX System. To treat the lead-in, or training subjects, each investigator will be proctored by another physician who has sufficient experience with the use of cPAX System.

Please be advised that the results from these studies should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a HDE Supplement.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the HDE.

Within 30 days of your receipt of this letter, you must submit a HDE supplement that includes a complete protocol of your post-approval study. Your HDE supplement should be clearly labeled as a "Post-Approval Study Protocol" and submitted in triplicate to the address below. Please reference the HDE number above to facilitate processing. If there are multiple protocols being finalized after HDE approval, please submit each protocol as a separate HDE supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2)

The sale, distribution, and use of this device are limited to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. In addition, in order to ensure the safe use of the device, FDA has further restricted the device within the meaning of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act insofar as (1) the labeling shall specify the training requirements for practitioners who may use the device as approved in this order and (2) the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

FDA wishes to remind you that failure to comply with any postapproval requirement constitutes a ground for withdrawal of the HDE. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

CDRH will notify the public of its decision to approve your HDE by making available a summary of the safety and probable benefit of the device upon which the approval was based. The

information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm>. Written requests for this information can also be made to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the HDE number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

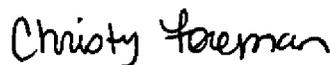
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this HDE submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when HDE applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

Any information to be submitted to FDA regarding this HDE should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above HDE number to facilitate processing:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approvable letter, please contact Chandramallika (Molly) Ghosh, Ph.D., DABT at (301) 796-6610.

Sincerely yours,



Christy Foreman
Acting Director
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure
HDE Conditions of Approval