

FDA may not approve an ANDA that does not refer to a listed drug.

NORMODYNE (labetalol hydrochloride) injection, 5 mg/mL, is the subject of NDA 018686, held by Schering Corp., and initially approved on August 1, 1984. NORMODYNE is indicated for control of blood pressure in severe hypertension.

In a letter dated September 28, 2004, Schering Corp. notified FDA that NORMODYNE (labetalol hydrochloride) injection, 5 mg/mL, was being discontinued and requested withdrawal of NDA 018686 for NORMODYNE (labetalol hydrochloride), and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. In the **Federal Register** of June 16, 2006 (71 FR 34940), FDA announced that it was withdrawing approval of NDA 018686, effective June 16, 2006.

Nexsen Pruet, LLC, submitted a citizen petition dated February 4, 2021 (Docket No. FDA-2021-P-0162), under 21 CFR 10.30, requesting that the Agency determine whether NORMODYNE (labetalol hydrochloride) injection, 5 mg/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that NORMODYNE (labetalol hydrochloride) injection, 5 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal NORMODYNE (labetalol hydrochloride) injection, 5 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NORMODYNE (labetalol hydrochloride) injection, 5 mg/mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved

by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-10594 Filed 5-19-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2494]

Peripheral Vascular Atherectomy Devices—Premarket Notification Submissions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Peripheral Vascular Atherectomy Devices—Premarket Notification Submissions." This guidance provides updated recommendations for premarket submissions for a new or modified peripheral vascular atherectomy device.

DATES: The announcement of the guidance is published in the **Federal Register** on May 20, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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> 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 Docket No. FDA-2018-D-2494 for "Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions." Received comments 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, 240-402-7500.

- **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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jhumur Banik, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2550, Silver Spring, MD 20993–0002, 240–402–5239.

SUPPLEMENTARY INFORMATION:

I. Background

Atherectomy is an interventional procedure performed to remove atherosclerotic plaque from diseased arteries. FDA has developed this guidance for members of industry who submit and FDA staff who review premarket submissions for atherectomy devices used in the peripheral vasculature. This guidance is intended to provide recommendations for information to include in premarket notifications (510(k)) for peripheral vascular atherectomy devices (e.g., descriptive characteristics, labeling, biocompatibility, sterility, nonclinical, animal, and clinical performance testing).

FDA incorporated the information in the draft guidance entitled “Select Updates for Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions” into the final guidance document after issuing these select updates for public comment. FDA did not receive any comments on the draft guidance that appeared in the **Federal Register** of July 27, 2018 (83 FR 35658). FDA has incorporated the recommendations in the draft select updates into the existing final guidance without significant changes. FDA did not substantively change the sections of the existing atherectomy guidance that were not affected by the select update.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the

requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov> and at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of “Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 16013 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part/section or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
812	Investigational Device Exemption	0910–0078
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
807, subparts A through D	Electronic Submission of Medical Device Registration and Listing.	0910–0625
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards.	0910–0755
56	Institutional Review Boards	0910–0130
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119
801.150(a)(2) and (e)	Agreement for Shipment of Devices for Sterilization	0910–0131
“Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”.	Q-submissions	0910–0756

Dated: May 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-10592 Filed 5-19-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1130]

Implanted Brain-Computer Interface Devices for Patients With Paralysis or Amputation—Non-Clinical Testing and Clinical Considerations; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation—Non-Clinical Testing and Clinical Considerations.” Implanted brain-computer interface (BCI) devices are neuroprostheses that interface with the central or peripheral nervous system to restore lost motor and/or sensory capabilities in patients with paralysis or amputation. This guidance provides recommendations for nonclinical testing and study design considerations for investigational device exemptions feasibility and pivotal clinical studies.

DATES: The announcement of the guidance is published in the **Federal Register** on May 20, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

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

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- *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-2014-N-1130 for “Implanted Brain-Computer Interface(BCI) Devices for Patients with Paralysis or Amputation—Non-clinical Testing and Clinical Considerations.” Received comments 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, 240-402-7500.

- **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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the

SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation—Non-clinical Testing and Clinical Considerations” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Vivek Pinto, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4108, Silver Spring, MD 20993-0002, 301-796-6610.

SUPPLEMENTARY INFORMATION:

I. Background

The field of implanted BCI devices is progressing rapidly from fundamental neuroscience discoveries to translational applications and market access. Implanted BCI devices have the potential to bring benefit to people with severe disabilities by increasing their ability to interact with their environment, and consequently, providing new independence in daily life. On November 21, 2014, the Center for Devices and Radiological Health (CDRH) held an open public workshop with the aim of fostering an open discussion on the scientific and clinical considerations associated with the