

FDA recently approved for marketing the medical device, NEURX DIAPHRAGM PACING SYSTEM. NEURX DIAPHRAGM PACING SYSTEM is indicated to allow patients with stable, high spinal cord injuries and with stimulatable diaphragms to breathe without the assistance of a mechanical ventilator for at least 4 continuous hours a day. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NEURX DIAPHRAGM PACING SYSTEM (U.S. Patent No. 5,472,438) from Case Western Reserve University, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 17, 2010, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of NEURX DIAPHRAGM PACING SYSTEM represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for NEURX DIAPHRAGM PACING SYSTEM is 5,166 days. Of this time, 4,830 days occurred during the testing phase of the regulatory review period, while 336 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective:* April 28, 1994. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective April 28, 1994.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e):* July 18, 2007. FDA has verified the applicant's claim that the premarket approval application (PMA) for NEURX DIAPHRAGM PACING SYSTEM (PMA H070003) was initially submitted July 18, 2007.

3. *The date the application was approved:* June 17, 2008. FDA has verified the applicant's claim that PMA H070003 was approved on June 17, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and

Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,737 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by November 2, 2010. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 2, 2011. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 13, 2010.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2010-22081 Filed 9-2-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0579]

#### International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 11 on Capillary Electrophoresis General Chapter; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 11: Capillary Electrophoresis General Chapter." The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance provides the results of the ICH Q4B evaluation of the Capillary Electrophoresis General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. This guidance is in the form of an annex to the core guidance on the Q4B process entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions" (the core ICH Q4B guidance).

**DATES:** Submit either electronic or written comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

*Regarding the guidance:* Robert H. King, Sr., Center for Drug Evaluation and Research (HFD-003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993-0002, 301-796-1242, or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0373.

*Regarding the ICH:* Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

**SUPPLEMENTARY INFORMATION:****I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH

sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of December 17, 2009 (74 FR 66981), FDA published a notice announcing the availability of a draft tripartite guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 11: Capillary Electrophoresis General Chapter." The notice gave interested persons an opportunity to submit comments by February 16, 2010.

After consideration of the comments received and revisions to the guidance, a final draft guidance entitled "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 11: Capillary Electrophoresis General Chapter" was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in June 2010.

The guidance provides the specific evaluation outcome from the ICH Q4B process for the Capillary Electrophoresis General Chapter harmonization proposal originating from the three-party PDG. This guidance is in the form of an annex to the core ICH Q4B guidance made available in the **Federal Register** of February 21, 2008 (73 FR 9575). When implemented, the annex will provide guidance for industry and regulators on the use of the specific pharmacopoeial texts evaluated by the ICH Q4B process. Following receipt of comments on the draft, no substantive changes were made to the annex.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: August 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket Nos. FDA-2010-M-0244, FDA-2010-M-0220, FDA-2010-M-0219, FDA-2010-M-0242, FDA-2010-M-0261, FDA-2010-M-0262, FDA-2010-M-0264, FDA-2010-M-0294, FDA-2010-M-0285]

**Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

**FOR FURTHER INFORMATION CONTACT:** Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993-0002, 301-796-6570.

**SUPPLEMENTARY INFORMATION:**