DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–P–0176]

SEDASYS Computer-Assisted Personalized Sedation System; Ethicon Endo-Surgery, Inc.'s, Petition for Review of FDA's Denial of Premarket Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it intends to refer for review before an advisory committee Ethicon Endo-Surgery Inc.'s (EES's), petition for review of the Agency's denial of premarket approval for its SEDASYS computer-assisted personalized sedation system (SEDASYS system).

ADDRESSES: Submissions related to the petition should be filed with the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tarita Rooths, Regulations, Policy, and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–9138.

SUPPLEMENTARY INFORMATION: On February 26, 2010, the Center for Devices and Radiological Health (CDRH) issued a not approvable letter in response to the premarket approval application (PMA) (PMA P080009) submitted by EES for the SEDASYS system. The SEDASYS system is intended for use by gastroenterologists as a drug-delivery system for the administration of propofol for minimal-to-moderate sedation in healthy patients undergoing a colonoscopy or esophagogastroduodenoscopy. CDRH determined the PMA for the SEDASYS system not to be approvable under § 814.44(f) (21 CFR 814.44(f)) because it concluded that the data and information offered in support of the PMA did not provide a reasonable assurance that the device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling, as required by section 515(d)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

On March 25, 2010, EES requested administrative review of the not approvable letter. Submitted in the form of a petition for reconsideration under 21 CFR 10.33 (*see* § 814.44(f)(2)), EES's request stated that, in accordance with § 814.44(f), EES considered the not approvable letter to be a denial of approval of PMA P080009 under § 814.45 (21 CFR 814.45). Pursuant to section 515(d)(4) of the FD&C Act, EES requested review of this denial under section 515(g)(2) (21 U.S.C. 360e(g)(2)) of the FD&C Act.

Accordingly, as required by § 814.45(e)(3), CDRH issued an order denying approval of the PMA for the SEDASYS system on October 26, 2010 (Ref. 1). Pursuant to section 515(g)(2) of the FD&C Act, on November 5, 2010, FDA granted EES's petition for review of the order denying PMA P080009.

In accordance with section 515(g)(2) of the FD&C Act, the Commissioner of Food and Drugs (the Commissioner) or her designee is referring PMA P080009 and the basis for the order denying its approval to an advisory committee of qualified experts. After independent study of the data and information furnished by the parties, and other data and information before it, the advisory committee will submit to the Commissioner a report and recommendation with respect to the order, together with the underlying data and information and a statement of the reasons or basis for the recommendation (section 515(g)(2)(A) of the FD&C Act). The Commissioner will provide a copy of that report and recommendation to the petitioner (id.), as well as to CDRH. At this time, the Commissioner also anticipates offering both the petitioner and CDRH the opportunity to submit comments on the report and recommendation before the final order is rendered. In keeping with section 515(g)(2)(C) of the FD&C Act, the Commissioner will make the report and recommendation public and issue an order either affirming or reversing the denial of approval.

In 1999, FDA established a standing advisory committee known as the Medical Devices Dispute Resolution Panel to provide advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies (see the charter for the Medical Devices Advisory Committee (MDAC charter)) (Ref. 2). In a guidance document entitled "Resolving Scientific Disputes Concerning the Regulation of Medical Devices, A Guide to Use of the Medical Devices Dispute Resolution Panel" (July 2, 2001) (the Guidance), FDA clarified that the Medical Devices Dispute Resolution Panel was established, in part, to receive referrals of petitions for advisory committee review under section 515(g)(2) of the FD&C Act (Ref. 3).

Accordingly, the Commissioner will refer EES's petition for review to this advisory committee for a report and recommendation with respect to the order denying PMA P080009. The Office of the Commissioner will select the temporary members of, and any consultants to, the advisory committee, and otherwise ensure that the proceeding is conducted in accordance with section 515(g)(2) of the FD&C Act, the Federal Advisory Committee Act, FDA's regulations in 21 CFR part 14 governing its public advisory committees, the MDAC charter, and any other applicable laws or regulations. The Office of the Commissioner will also perform the other duties assigned to FDA under section 515(g)(2) of the FD&C Act. The Office of the Commissioner will publish a **Federal Register** notice concerning the advisory committee meeting at a later date.

Although no statute or regulation requires that separation of functions be applied to this proceeding, the Agency is observing separation of functions as a matter of policy in this matter. As the Center responsible for the action under review, CDRH will be, like EES, a party to the advisory committee hearing and will be responsible for presenting its position at that meeting.

In addition, as a corollary to its decision to observe a separation of functions, until the Commissioner issues an order either affirming or reversing the order denying approval of PMA P080009, the Office of the Commissioner will not engage in any *ex parte* communication (see 21 CFR 10.3(a)) with anyone participating as a party to the hearing or any person outside the Agency with respect to the matter under consideration.[1] Any written *ex parte* communication will be immediately served on the two parties and filed in the docket. Any oral *ex parte* communication will be immediately memorialized in writing, served on both parties to the hearing, and filed in the docket.

All documents filed in this matter are filed under Docket No. FDA–2010–P–0176 and are available for public review in the Division of Dockets Management (*see* **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain

[1] Communications regarding procedural matters between the Office of the Commissioner and the advisory committee will not be treated as *ex parte* communications.

documents in the docket at *http://www.regulations.gov*.

References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, under Docket No. FDA–2010–P–0176 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from Christy Foreman, FDA, CDRH, to Ken Charak, Ethicon Endo-Surgery, Inc., containing the order denying approval of the PMA for the SEDASYS system, October 26, 2010.

2. Charter Medical Devices Advisory Committee; Charter Amendment, Medical Devices Advisory Committee; FDA; July 15, 2008, *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ucm124098.htm*.

3. "Resolving Scientific Disputes Concerning the Regulation of Medical Devices, A Guide To Use of the Medical Devices Dispute Resolution Panel; Final Guidance for Industry and FDA" FDA, CDRH; July 2, 2001, *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*.

Dated: March 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–6520 Filed 3–18–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–E–0400]

Determination of Regulatory Review Period for Purposes of Patent Extension; VPRIV

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VPRIV and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written petitions along with three copies and 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product VPRIV (velaglucerase alfa). VPRIV is indicated for long-term enzyme replacement therapy for pediatric and adult patients with type 1 Gaucher Disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VPRIV (U.S. Patent No. 7,138,262) from Shire Human Genetic Therapies, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 30, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VPRIV represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VPRIV is 2,221 days. Of this time, 2,041 days occurred during the testing phase of the regulatory review period, while 180 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* January 30, 2004. The applicant claims May 20, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 30, 2004, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* August 31, 2009. FDA has verified the applicant's claim that the new drug application (NDA) for VPRIV (NDA 22–575) was initially submitted on August 31, 2009.

3. *The date the application was approved:* February 26, 2010. FDA has verified the applicant's claim that NDA 22–575 was approved on February 26, 2010.

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 687 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 May 20, 2011. 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 September 19, 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.