DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–E–0296]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VOTRIENT 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 VOTRIENT (pazopanib hydrochloride). VOTRIENT is a kinase inhibitor indicated for treatment of patients with advanced renal cell carcinoma. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VOTRIENT (U.S. Patent No. 7,105,530) from GlaxoSmithKline, LLC., 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 VOTRIENT 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 VOTRIENT is 2,568 days. Of this time, 2,263 days occurred during the testing phase of the regulatory review period, while 305 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:* October 10, 2002. The applicant claims October 9, 2002, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 10, 2002, 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:* December 19, 2008. FDA has verified the applicant's claim that the new drug application (NDA) for Votrient (NDA 22–465) was submitted on December 19, 2008.

3. *The date the application was approved:* October 19, 2009. FDA has verified the applicant's claim that NDA 22–465 was approved on October 19, 2009.

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 719 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 July 5, 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 October 31, 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 *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 15, 2011.

Jane A. Axelrad,

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

[FR Doc. 2011–10870 Filed 5–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Advisory Committee; Medical Imaging Drugs Advisory Committee; Reestablishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

reestablishment of the Medical Imaging Drugs Advisory Committee in the Division of Advisory Committee and Consultants Management, Center for Drug Evaluation and Research.

FOR FURTHER INFORMATION CONTACT: Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2424, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *MIDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463 (5 U.S.C. app. 2)); section 904 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 394), as amended by the Food and Drug Administration Revitalization Act (Pub. L. 101–635); and 21 CFR 14.40(b), FDA is announcing the reestablishment of the Medical Imaging Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). A notice announcing a request for nominations for members and representatives on the committee as well as a final rule adding the committee to the current list of committees in 21 CFR 14.100 will be published at a later date.

The Medical Imaging Drugs Advisory Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology and makes appropriate recommendations to the Commissioner.

The Medical Imaging Drugs Advisory Committee shall consist of a core of 12 voting members including the chair. Members and the chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of nuclear medicine, radiology, epidemiology or statistics, and related specialties. Almost all non-Federal members of this committee serve as special Government employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the committee may include one nonvoting member who is identified with industry interests.

This notice is given under the Federal Advisory Committee Act and 21 CFR part 14, relating to advisory committees.

Dated: April 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–10813 Filed 5–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

2011 Parenteral Drug Association/Food and Drug Administration Glass Quality Conference; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA), in cosponsorship with the Parenteral Drug Association (PDA), is announcing a public conference entitled "PDA/FDA Glass Quality Conference—Best Practices to Prevent and/or Detect At-Risk Glass Packaging."

Date and Time: The public conference will be held on May 23, 2011, from 7 a.m. to 6:30 p.m. and May 24, 2011, from 7 a.m. to 4:30 p.m.

Location: The public conference will be held at the Key Bridge Marriott Hotel, 1401 Lee Highway, Arlington, VA 22209, 1–703–524–6400, FAX: 1–703–524–8964.

Contact Person: Wanda Neal, Parenteral Drug Association (PDA), PDA Global Headquarters, Bethesda Towers, 4350 East-West Highway, suite 200, Bethesda, MD 20814, 1–301–656–5900, extension 111, FAX: 1–301–986–1093, e-mail: *neal@pda.org.*

Accommodations: Attendees are responsible for their own accommodations. To make reservations at the Key Bridge Marriott Hotel, at the reduced conference rate, contact the Key Bridge Marriott Hotel (see *Location*), citing meeting code "PDA." Room Rates are: Single/Double: $229, plus applicable state and local. Reservations can be made on a space and rate availability basis.

Registration: You are encouraged to register at your earliest convenience. The PDA registration fees cover the cost of facilities, materials, and breaks. Seats are limited; therefore, submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Onsite registration will be available on a space available basis on the day of the public conference beginning at 7 a.m. on May 23, 2011. The cost of registration is as follows:

PDA Members	$1,895.00
PDA Non-Members.	$2,144.00
Government/Health Authority PDA Member	$700.00
Government/Health Authority PDA Non-Member	$700.00
PDA Member Academic	$700.00
PDA Non-Member Academic/ Health Authority	$780.00
PDA Member Students	$280.00
PDA Non-Member Students	$310.00

If you need special accommodations due to a disability, please attach a written description of your needs with your registration form. Specific questions can be e-mailed to *day@pda.org.*

Registration Instructions: To register, please submit your registration form online *http://www.pda.org/glassquality2011* or by mail to: PDA Global Headquarters, 4350 East West Highway, suite 150, Bethesda, MD 20814. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register.**)

SUPPLEMENTARY INFORMATION: Due to recent glass packaging quality issues and recalls related to defects or incompatibilities with finished product over the shelf life, pharmaceutical manufacturers and glass suppliers have recognized the need for improvements in glass packaging and glass handling practices throughout the product life cycle. Appropriate standards, glass supplier reliability, and best practices on glass handling and distribution are all necessary elements in the maintenance of container integrity and product sterility assurance throughout the product life cycle of sterile injectable pharmaceutical and biopharmaceutical products. The 2-day public conference will cover:

- Current issues with glass packaging,
- Best practices on glass handling,
- Current expectations for incoming glass and pharmaceutical product packaging,
- How to establish an effective glass supplier relationship for product improvement, and
- Improvements in glass manufacturing, characterization, handling or packaging.

The conference program will include an exhibition on May 23 and 24, 2011.

Dated: April 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–10764 Filed 5–3–11; 8:45 am]

BILLING CODE 4160–01–P