promote and implement collaborative efforts.

Divison of Media Relations (CA33). (1) Provides leadership through the development of policies and practices for effective communication through the media; (2) develops strategies for the Director, CDC, and other CDC leaders in developing and disseminating information through the media; (3) coordinates the development and dissemination of media information among CIO's and between CDC and HHS; (4) assists CIO's in meeting their press-related needs and priorities; (5) provides training and technical assistance to CDC staff about media relations; (6) provides advice and consultation to the Director and oversight of crosscutting issues related to communication; (7) provides the central point of contact to CDC for media representatives; (8) provides timely, thorough, and appropriate responses to inquiries by media representatives; (9) employs the latest technologies to serve CDC and media constituents best; (10) conducts special activities to develop relationships with media representatives; (11) periodically assesses the conduct of CDC media relations activities, including feedback from consumers.

Dated: May 15, 1997.

David Satcher,

Director.

[FR Doc. 97–13965 Filed 5–28–97; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0108]

Determination of Regulatory Review Period for Purposes of Patent Extension; PATANOL™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PATANOL™ 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 Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

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 Commissioner 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 PATANOL™ (olopatadine hydrochloride). PATANOL™ is indicated for the temporary prevention of itching of the eye due to allergic conjunctivitis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PATANOL™ (U.S. Patent No. 5,116,863) from Alcon Laboratories, 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 April 1, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of PATANOL™ represented the first permitted commercial marketing or use of the product. Shortly 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 PATANOL™ is 1,064 days. Of this time, 739 days occurred during the testing phase of the regulatory review period, while 325 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 (21 U.S.C. 355(i)) became effective*: January 21, 1994. The applicant claims January 20, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 21, 1994, 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 Federal Food, Drug, and Cosmetic Act*: January 29, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for PATANOL™ (NDA 20–688) was initially submitted on January 29, 1996.

3. *The date the application was approved*: December 18, 1996. FDA has verified the applicant's claim that NDA 20–688 was approved on December 18, 1996.

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 571 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 28, 1997, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 25, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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.

Comments and petitions should be submitted to the Dockets Management

Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 20, 1997.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97–14108 Filed 5–28–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0204]

QLT Phototherapeutics, Inc.; Premarket Approval of OPTIGUIDE™ Fiber Optic Diffuser (Models DCYL 10, DCYL 15, and DCYL 25), Coherent Lambda Plus™ PDL1 and PDL2 Photodynamic Lasers, and 600 Series Dye Modules (Models 630 and 630 XP) and Series 700 and 800 KTP/532® and KTP/YAG™ Surgical Lasers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the applications by QLT Phototherapeutics, Inc., submitted by Hogan & Hartson, Washington, DC on behalf of QLT Phototherapeutics, Inc., Vancouver, Canada, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the following devices which constitute the device portion of a combination drug/device product: OPTIGUIDE™ Fiber Optic Diffuser DCYL Series (Models DCYL 10, DCYL 15, and DCYL 25); Coherent Lambda Plus™ PDL1 and PDL2 Photodynamic Lasers; and 600 Series Dye Modules (Models 630 and 630 XP) and Series 700 and 800 KTP/532® and KTP/YAG™ Surgical Lasers. These devices are to be used with the drug PHOTOFRIN® under conditions specified in the drug labeling. After reviewing the recommendation of the Oncologic Drugs Advisory Committee operating under the authority of the Inter Agency Agreement regarding combination drug/device products, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 27, 1995, of the approval of the applications.

DATES: Petitions for administrative review by June 30, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard P. Felten, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1307.

SUPPLEMENTARY INFORMATION: On April 13, 1994, Hogan & Hartson, Washington, DC 20004–1109, submitted to CDRH, on behalf of QLT Phototherapeutics, Inc., Vancouver, Canada, applications for premarket approval of a combination drug/device product which included the following devices for use with the drug PHOTOFRIN®: (1) OPTIGUIDE™ Fiber Optic Diffuser DCYL Series; (2) Coherent Lambda Plus™ PDL1 and PDL2 Photodynamic Lasers; and (3) 600 Series Dye Modules (Models 630 and 630 XP) and Series 700 and 800 KTP/532® and KTP/YAG™ Surgical Lasers.

The Fiber Optic Diffuser is indicated as a delivery system for use in Photodynamic Therapy with PHOTOFRIN® for palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy. The laser systems are indicated for use in Photodynamic Therapy as sources for the photoactivation of PHOTOFRIN® for palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy.

On September 21, 1995, the Immunology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, operating under the authority of the Inter Agency Agreement for combination drug/device products, reviewed and recommended approval of the applications. On December 27, 1995, CDRH approved the applications by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

Summaries of the safety and effectiveness data on which CDRH based its approval are on file in the Dockets Management Branch (address above) and are available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve these applications. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before June 30, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the devices and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 18, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–13958 Filed 5–28–97; 8:45 am]

BILLING CODE 4160–01–F