

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 ULTIVA™ (remifentanyl hydrochloride). ULTIVA™ is indicated for intravenous administration as follows: (1) As an analgesic agent for use during the induction and maintenance of general anesthesia for inpatient and outpatient procedures, and for continuation as an analgesic into the immediate postoperative period under the direct supervision of an anesthesia practitioner in a postoperative anesthesia care unit or intensive care setting; and (2) as an analgesic component of monitored anesthesia care. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ULTIVA™ (U.S. Patent No. 5,019,583) from Glaxo Wellcome, 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 November 4, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ULTIVA™ 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 ULTIVA™ is 2,222 days. Of this time, 1,920 days occurred during the testing phase of the regulatory review period, while 302 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:* June 14, 1990. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on June 14, 1990.

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: September 15, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for ULTIVA™ (NDA 20-630) was initially submitted on September 15, 1995.

3. *The date the human drug was approved:* July 12, 1996. FDA has verified the applicant's claim that NDA 20-630 was approved on July 12, 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 1,088 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 14, 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 May 5, 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: January 31, 1997.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

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Health Care Financing Administration

[Document Identifier: HCFA-9026]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS. In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Health Care Financing Administration (HCFA),

Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

HCFA-9026 Type of Information Collection Request: Reinstatement, without change, of previously approved collection for which approval has expired; **Title of Information Collection:** Intermediary Request to Hospitals for Medical Information on Inpatient Claims for Statutorily Excluded Services/SSA 1862; 42 CFR 411.15; FR Vol. 60, No. 181; **Form No.:** HCFA-9026; **Use:** This information request is to enable intermediaries to obtain hospital medical records for inpatient claims involving statutorily excluded services and other non-covered services and devices. 42 CFR 411.15 is the regulation supporting this collection of information; **Frequency:** On occasion; **Affected Public:** Business or other for profit, not for profit institutions, State, local, or tribal governments, Federal government; **Number of Respondents:** 5,258; **Total Annual Responses:** 20,355; **Total Annual Hours:** 5,088.

To obtain copies of the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcf.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: February 3, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

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