might include: What is the relationship between the availability of tools for assessing particular outcomes and a community's efforts to achieve those outcomes? From a systemic perspective, how does the definition of outcomes, or the operationalization of them, have impact on the system's delivery of services and the success of particular populations achieving the outcomes?

Over-represented populations and special populations (i.e., racial and ethnic groups, children with disabilities): With continuing concern about over-representation, research questions might include: What are the characteristics of the system or the context that may contribute to the over-representation of some populations in child protective service caseloads? How do systems achieve a better understanding of the dynamics of the communities that are over-represented? How are clients assessed in order to generate knowledge about these populations that is formed from appropriate cultural and sociological perspectives?

NCCAN/CB is interested in the safety and well-being of immigrant children and their families, as a special population. Questions might include explorations of service utilization, outreach, and cultural context. More specific examples of research questions might include: What are the relationships between child safety and well-being, child protective services, the characteristics and needs of the children and families themselves, and the communities in which they reside? How are the needs of immigrant children and their families identified and assessed? What are effective maltreatment prevention and treatment program models for these populations?

Secondary Analysis: NCCAN/CB seeks comments regarding the interest of the field for funding of secondary analyses of federally-financed data collections and existing datasets. Opportunities here exist in the analysis of, for example, Head Start data, data from the Adoption Foster Care Analysis and Reporting System (AFCARS), the 1994 National Study of Protective, Preventive and Reunification Services Delivered to Children and their Families, the National Child Abuse and Neglect Data System (NCANDS), and the National Incidence Study (NIS), regarding specific field-generated or federally-generated research inquiries related to child maltreatment. Comments should include (1) suggestions for minimal award sizes and (2) suggestions for application strategies that reduce the burden of applying for these small-amount grants.

Triage: Triage, here, is used to describe a differentiated response service-entry or resource allocation model for handling child abuse and neglect reports. Some triage models include assignment to service prior to investigation for some classes of reports. Research interests include questions about: The effects of a triage process on child safety and child and family well-being, caseload sizes, and resource allocation; and evaluations of the impact and efficacy of criteria, tools, and protocols for case assignment, safety and risk assessment. Does a triage approach result in changes in system responses, client behavior (i.e., recidivism), changes in public perception of CPS, or changes in clients' perceptions of CPS responsiveness to their needs or to the perception of a punitive nature of CPS service?

Welfare Reform and System Changes: The impact of recent changes in family support entitlements, block granting of welfare funds, work requirements, child care needs, and other systemic changes is unknown. NCCAN/CB is interested in research which explores the interactions of these changes in welfare policy at the state and local level with child safety in general and the protective needs of children in particular. States have a range of options available to them as they implement new welfare programs. Questions might include: How do these policy choices affect child protective services agencies' ability to protect children? What are the impacts on case loads, case characteristics, and system entry and exit, for example, of family caps, time limits, and the transition to work?

C. Field Initiated Research on Child Abuse and Neglect

The generation of new knowledge for understanding critical issues in child abuse and neglect improves prevention, identification, assessment, and treatment. Research areas to be addressed may be those that will expand the current knowledge base, build on prior research, contribute to practice enhancements, inform policy, improve science, and provide insights into new approaches to the assessment, prevention, intervention, and treatment of child maltreatment (i.e., physical abuse, sexual abuse, emotional maltreatment, or neglect) on any of the topics listed in (A) Legislative Topics, (B) Other Topics, above, or any other child maltreatment topic.

In addition to the topics cited above, practitioners and researchers are encouraged to propose other relevant subjects for research topics.

(Catalog of Federal Domestic Assistance Program Number 93.670, Child Abuse and Neglect Prevention and Treatment)

Dated: February 7, 1997.

James A. Harrell,

Deputy Commissioner, Administration on Children, Youth and Families.

[FR Doc. 97–3469 Filed 2–11–97; 8:45 am]

BILLING CODE 4184–01–P

Food and Drug Administration

[Docket No. 96E–0385]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ULTIVA™ 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 ULTIVA™ (remifentanil 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.

[FR Doc. 97–3417 Filed 2–11–97; 8:45 am]

BILLING CODE 4160–01–F

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@hcfa.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.

[FR Doc. 97–3498 Filed 2–11–97; 8:45 am]

BILLING CODE 4120–03–P