No.: CMS–R–306 (OMB# 0938–0833); *Use:* Psychiatric residential treatment facilities are required to report deaths, serious injuries and attempted suicides to State Medicaid Agency and Protection and Advocacy Organization. They are also required to provide residents restraint and seclusion policy in writing and to document resident record of all activities involving use of restraint and seclusion; *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not for profit institutions; *Number of Respondents:* 500; *Total Annual Responses:* 2,600,000; *Total Annual Hours:* 877,750. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at *http://www.hcfa.gov/regs/prdact95.htm*, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: September 11, 2001.

John P. Burke, III,

Reports Clearance Officer, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 01–23577 Filed 9–20–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Fund Annual Report (ACF–700).

OMB No.: 0980–0241.

Description: The Child Care and Development Fund (CCDF) report requests annual tribal aggregate information on services provided through the CCDF which is required by the Child Care and Development Block Grant (CCDBG) Final Rule (45 CFR parts 98 and 99). Tribes are required to submit annual aggregate data appropriate to tribal programs on children and families receiving CCDF-funds or CCDBG funded child care services. The CCDBG statute and regulations also require Tribal Lead Agencies to submit a supplemental narrative as part of the ACF–700 report. This narrative describes general child care activities and actions in the Tribal Lead Agency's service area and is not restricted to CCDF-funded child care activities. Instead this description is intended to address all child care available in the Tribal Lead Agency's service area. The ACF–700 and supplemental narrative report will be included in the Secretary's report to Congress, as appropriate, and will be shared with all Tribal Lead Agencies to inform them of CCDF or CCDBG-funded activities in other tribal programs.

Respondents: Tribal CCDF Programs (257 in total).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CCDF Annual report	257	1	35	8,995
Estimated Total Annual Burden Hours				8,995

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: September 17, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–23646 Filed 9–20–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E–0089]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Kaletra 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 that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments..*

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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