rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities.'' This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the **Federal Register**.

The Secretary of the Treasury has certified a rate of 12% for the quarter ended September 30, 2004. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of the change.

Dated: November 8, 2004.

George Strader,

Deputy Assistant Secretary, Finance.

[FR Doc. 04–25357 Filed 11–15–04; 8:45 am]

BILLING CODE 4150–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Low Income Home Energy Assistance Program (LIHEAP) Grantee Survey.

OMB No.: 0970–0076.

Description: The LIHEAP Grantee Survey is an annual data collection activity, which is sent to the 50 States and the District of Columbia grantees administering the Low Income Home Energy Assistance Program (LIHEAP). The survey is mandatory in order that national estimates of the sources and uses of LIHEAP funds can be calculated in a timely manner; a range can be calculated of state average LIHEAP benefits; and maximum income cutoffs for 4-person households can be obtained for estimating the number of low-income households that are income eligible for LIHEAP under State income standards.

Respondents: 50 States and the District of Columbia.

Annual Burden Estimates:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Survey	51	1	3.4	173.4

Estimated Total Annual Burden Hours: 173.4.

Additional Information: The need for the survey is to provide the Administration and Congress with fiscal estimates in time for hearings about LIHEAP appropriations and program performance. The information also is included in the Department's annual LIHEAP Report to Congress. Survey information also will be posted on Office of Community Services LIHEAP web site for access by grantees and other interested parties.

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All request should be identified by the title of the information collection. E-mail address: *grjohnson@acf.hhs.gov.*

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, Attn: Desk Officer for ACF, e-mail address: *Katherine_T._Astrich@omb.eop.gov.*

Dated: November 9, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–25341 Filed 11–15–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004P–0051]

Determination That DYCLONE (Dyclonine Hydrochloride) 0.5% and 1.0% Topical Solutions Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that DYCLONE (dyclonine hydrochloride (HCl)) 0.5% and 1.0% Topical Solutions were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for DYCLONE HCl 0.5 and 1.0% Topical Solutions.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).