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).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

DYCLONE (dyclonine HCl) 0.5% and 1.0% Topical Solutions were the subject of approved NDA 9–925 held by AstraZeneca LP. DYCLONE Topical Solutions were labeled for anesthetizing accessible mucus membranes prior to various endoscopic procedures. DYCLONE 0.5% Topical Solution was also labeled to block the gag reflex, to relieve the pain of oral ulcers or stomatitis, and to relieve pain associated with ano-genital lesions.

In a citizen petition dated February 3, 2004 (Docket No. 2004P–0051/CP1), submitted under 21 CFR 10.25(a) and 10.30, Arent Fox, PLLC, requested that the agency determine whether DYCLONE (dyclonine HCl) 0.5% and 1.0% Topical Solutions were withdrawn from the market for reasons of safety or effectiveness. In the **Federal Register** of February 11, 2002 (67 FR 6264), FDA withdrew approval of NDA 9–925 for DYCLONE 0.5% and 1.0% Topical Solutions after AstraZeneca notified the agency that DYCLONE was no longer being marketed under NDA 9–925 and requested withdrawal of that application.

The agency has determined that DYCLONE 0.5% and 1.0% Topical Solutions were not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that DYCLONE was withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that, for the reasons outlined in this notice, dyclonine HCl 0.5% and 1.0% topical solutions approved under NDA 9–925 were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DYCLONE (dyclonine HCl) 0.5% and 1.0% Topical Solutions in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DYCLONE (dyclonine HCl) 0.5% and 1.0% Topical Solutions may be approved by the agency.

Dated: November 8, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–25332 Filed 11–15–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Free Clinic—FTCA Deeming Application (OMB No. 0915–0293)—Extension

Congress legislated FTCA medical malpractice protection for free clinic volunteer health professionals through section 194 of the Health Insurance Portability and Accountability Act (HIPAA) amending Section 224 of the Public Health Service Act. Individuals eligible to participate in this program are health care practitioners volunteering at free clinics who meet specific eligibility requirements. If an individual meets all the requirements of this program they can be ''deemed'' to be a Federal employee. This deemed status is specifically to provide immunity from medical malpractice lawsuits as a result of the performance of medical, surgical, dental, or related activities within the scope of the volunteer's work at the free clinic.

The sponsoring free clinic entity must submit an application to the Health Resources and Services Administration (HRSA). This application will require information about the sponsoring free clinic's credentialing system, risk management practices, and quality assurance system in order to ensure the Government is not exposed to undue liability resulting from the medical malpractice coverage of non-qualified health care professionals. Attached to the application will be a listing of specific health care providers for whom the sponsoring free clinic is requesting deemed status.

Estimates of annualized reporting burden are as follows:

Type of form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
FTCA Deeming Application	600	1	600	5	3,000
Total	600		600		3,000