Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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Fox, PLLC, requested that the agency determine whether DYCLONE (dyclonine HCl) 0.5% and 1.0% Topical Solutions were withdrawn from the market for reasons of safety or effectiveness.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The agency has determined that DYCLONE 0.5% and 1.0% Topical Solutions were not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that DYCLONE was withdrawn from sale as a result of safety or effectiveness concerns.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literature and data for adverse event reports and has found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness.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the reasons outlined in this notice, dyclonine HCl 0.5% and 1.0% topical solutions approved under NDA 9–925 were not withdrawn from sale for reasons of safety or effectiveness.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

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 8, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–25403 Filed 11–15–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee D—Clinical Studies.

Date: December 8–10, 2004.

Time: 7 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Bethesda North Hotel and Conference Ctr., 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: William D. Merritt, PhD, Scientific Review Administrator, Research Programs Review Branch, National Cancer Institute, Division of Extramural Activities, 6116 Executive Blvd., 8th Floor, Bethesda, MD 20892–8328, (301) 496–9767, *wm63f@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 8, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–25345 Filed 11–15–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group Subcommittee C—Basic & Preclinical.

Date: December 8–10, 2004.

Time: 6 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Bethesda North Hotel and Conference Ctr., 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Michael B. Small, PhD, Scientific Review Administrator, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8127, Bethesda, MD 20892, (301) 402–0996, *smallm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 8, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–25350 Filed 11–15–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Review of Research Project Cooperative Agreements (U01s).

Date: December 9, 2004.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Hotel Rouge, 1315 16th Street, NW., Washington, DC 20036.

Contact Person: Keith A. Mintzer, PhD, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7186, MSC 7924, Bethesda, MD 20892, (301) 435–0280.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.389, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 8, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–25349 Filed 11–15–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.