

Thereafter, petitioner must advise the Department of any change of address, phone number, or attorney of record or other representative. We will not further process a Notice of Intent to File a Petition if we are unable to contact the petitioner or her/his attorney or other representative in the future because of a change in such information of which we were not informed. New name, address, phone number(s) or attorney or other representative information should be sent to the same addressee as will receive Notices of Intent to File a Petition.

The date of receipt of the Notice of Intent will be viewed as the date of filing for purposes of the 3-year time limit on filing petitions (section 105 of the act). The Notice of Intent will not activate Departmental consideration beyond sending an acknowledgment of its receipt since processing and consideration commence on the filing of an actual petition. The sending of the acknowledgment in no way implies that the petitioner has been determined to be eligible for a payment. The review period described in section 103(d) of the Act will begin on receipt of a full petition containing all information to be specified in future instructions. All filings are confidential and will be used only for authorized purposes.

Should funds be appropriated for the administrative costs of the program and for the payment of successful petitions, we will advise those who submit Notices of Intent of the content, format, and deadlines for future submissions related to the petition.

Dated: March 10, 1999.  
**Donna E. Shalala,**  
*Secretary of Health and Human Services.*  
 [FR Doc. 99-7221 Filed 3-23-99; 8:45 am]  
 BILLING CODE 4165-15-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 98N-1036]

**Vale Chemical Co., Inc., et al.;  
 Withdrawal of Approval of 13 New  
 Drug Applications and 1 Abbreviated  
 New Drug Application**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of 13 new drug applications (NDA's) and 1 abbreviated new drug application (ANDA). The basis for the withdrawals is that the holders of the applications have repeatedly failed to file required annual reports for these applications.

**EFFECTIVE DATE:** March 24, 1999.

**FOR FURTHER INFORMATION CONTACT:** Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** The holders of approved applications to

market new drugs or antibiotics for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of December 2, 1998 (63 FR 66549), FDA offered an opportunity for a hearing on a proposal to withdraw approval of 13 NDA's and 1 ANDA because the firms had failed to submit the required annual reports for these applications.

Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299, notified the agency that they no longer market the products for NDA's 50-088, 50-129, 50-189, 50-197, 50-305, and 50-319. Wyeth-Ayerst did not request a hearing and submitted a formal request for the agency to withdraw approval of the NDA's for these products.

The holders of the other eight applications did not respond to the notice of opportunity for a hearing. Failure to file a written notice of participation and request for a hearing as required by 21 CFR 314.200 constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the applications listed in the table of this document.

Application No.	Drug	Applicant
NDA 7-112	Nisaval (pyrilamine maleate) 25 milligram (mg) Tablets	Vale Chemical Co., Inc., 1201 Liberty St., Allentown, PA 18102.
NDA 11-863	Flavihist Cough Syrup	Boyle & Co., 6330 Chalet Dr., Los Angeles, CA 90022.
NDA 50-042	Potassium Penicillin G Diagnostic Sensitivity Powder, 20,000 units	Pfizer Inc., 235 East 42d St., New York, NY 10017-5755.
NDA 50-067	Compocillin-VK Chewable Wafers	Abbott Laboratories, 100 Abbott Park Rd., Abbott Park, IL 60064.
NDA 50-088	Unipen Injection	Wyeth-Ayerst Laboratories, P.O. Box 8299, Philadelphia, PA 19101-8299.
NDA 50-121	Compocillin-VK Tablets	Abbott Laboratories.
NDA 50-122	Compocillin-V Chewable Wafers	Do.
NDA 50-129	Pen-Vee Suspension and Drops	Wyeth-Ayerst Laboratories.
NDA 50-189	Omnipen Tablets	Do.
NDA 50-197	Unipen Injection	Do.
NDA 50-305	Unipen Capsules	Do.
NDA 50-319	Omnipen Chewable Tablets	Do.
NDA 50-413	Geopen Diagnostic Susceptibility Powder	Pfizer Inc.
ANDA 87-387	Aminophylline Injection USP, 25 mg/milliliter	Pharma-Serve, Inc., 218-20 98th Ave., Queens Village, NY 11429.

The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 355(e)), and under authority of 21 CFR 5.82, finds that the holders of the applications

listed in the table of this document have repeatedly failed to submit reports required by § 314.81. Therefore, under

this finding, approval of the applications listed in the table of this document, and all amendments and supplements thereto, is hereby withdrawn, effective March 24, 1999.

Dated: March 8, 1999.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 99-7124 Filed 3-23-99; 8:45 am]

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**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 E—Prevention & Control.

*Date:* April 28–30, 1999.

*Time:* 8:00 am to 5:00 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Mary C. Fletcher, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, EPN—Room 643G, Bethesda, MD 20814, 301/496-7413.

(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: March 18, 1999.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

[FR Doc. 99-7198 Filed 3-23-99; 8:45 am]

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**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:* April 14–15, 1999.

*Time:* 12:00 pm to 6:00 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

*Contact Person:* Martin H. Goldross, PHD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, Room 635 C, Rockville, MD 20852-7408, (301) 496-7930, mg85x@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: March 18, 1999.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

[FR Doc. 99-7199 Filed 3-23-99; 8:45 am]

BILLING CODE 4140-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Center for Research Resources; Notice of 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 open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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:* Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities.

*Date:* May 25–27, 1999.

*Open:* May 25, 1999, 8:00 am to 9:00 am.

*Agenda:* To discuss program planning and program accomplishments.

*Place:* Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Closed:* May 25, 1999, 9:00 am to Adjournment.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* D.G. Patel, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, Bethesda, MD 20892, (301) 435-0822.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: March 18, 1999.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

[FR Doc. 99-7201 Filed 3-23-99; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Center for Research Resources; Notice of 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 a meeting of the National Advisory Research Resources Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should