

and received comments may be seen in the office of the Hearing Clerk, address given above, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 8, 1978.

HOWARD R. ROBERTS,
Acting Director of Bureau of Foods.
[FR Doc. 78-6785 Filed 3-16-78; 8:45 am]

[4110-03]

**CARDIOVASCULAR DEVICE CLASSIFICATION
PANEL**

Meeting

AGENCY: Food and Drug Administration.

Committee name	Date, time, and place	Type of meeting and contact person
Cardiovascular Device Classification Panel.	Apr. 7, 9 a.m., room 1409, FB-8, 200 C St. SW., Washington D.C.	Open public hearing 9 to 10 a.m.; open committee discussion 10 a.m. to 2 p.m.; closed committee deliberations 2 to 4 p.m.; Glenn A. Rahmoeller (HFK-450), 5787 Georgia Ave., Silver Spring, Md. 20910, 301-427-7560.

General function of the committee. Reviews and evaluates available data concerning the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

Agenda—Open public hearing. Interested parties are encouraged to present information pertinent to this panel's tentative classification findings to the executive secretary. Those desiring to make formal presentations should notify the executive secretary by March 24, 1978 and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, references to any data to be relied on, and an indication of the approximate time required to make their comments.

Open committee discussion. During this portion of the meeting, panel members will review their classification recommendation for defibrillators, discuss labeling for defibrillators with a stored energy greater than 400 joules, review clinical data (if available) from testing of teflon-coated guide wires, and review guidelines for the clinical testing of pacemakers and oxygenators as required in support of premarket notification submissions (21 U.S.C. 360(k)).

Closed committee deliberations. The panel members will discuss suggestions from the sponsor of the Hunter-Sessions Vena Cava Balloon Occluder for revising the indications and caution statements.

The panel will also discuss transitional New Drug Applications (NDA's)

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also sets forth a summary of the procedures governing committee meetings and methods by which interested persons may participate in open public hearings conducted by the committees and is issued under section 10(a) (1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), and FDA regulations (21 CFR Part 14) relating to advisory committees. The following advisory committee meeting is announced:

for biological arterial grafts and supporting Investigational New Drug Applications (INDA's) for these products.

This portion of the meeting will be closed to permit discussion of trade secret data (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairman determines will facilitate the committee's work.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this FEDERAL REGISTER notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall

inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be obtained from the Public Records and Documents Center (HFC-18), 5600 Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR Part 14.

The Commissioner, with the concurrence of the Chief Counsel, has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA), as amended by the Government in the Sunshine Act (Pub. L. 94-409), permit such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient re-

cords, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, notably, deliberative sessions to formulate advice and recommendations to the agency on matters that do not independently justify closing.

Dated: March 10, 1978.

DONALD KENNEDY,
Commissioner of Food and Drugs.
[FR Doc. 78-7070 Filed 3-16-78; 8:45 am]

[4110-03]

[Docket No. 78C-0041]

KIRKER CHEMICAL CO.

Filing of Color Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Kirker Chemical Co. has filed a petition proposing the issuance of a regulation for the safe use of silver metal as a color additive in externally applied cosmetics.

FOR FURTHER INFORMATION CONTACT:

Gerard L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: In accordance with the Federal Food, Drug, and Cosmetic Act (sec. 706(d), 74 Stat. 402-403 (21 U.S.C. 376(d))) notice is given that a color additive petition (CAP 8C0137) has been filed by Kirker Chemical Co., 1 East 11th Street, P.O. Box 365, River Street Station, Paterson, N.J. 07524, proposing the issuance of a color additive regulation under Part 73 (21 CFR Part 73) to provide for the safe use and exemption from certification of crystalline silver metal to be used as a color additive in fingernail polish.

The environmental impact analysis report and other relevant material have been reviewed, and it has been determined that the proposed use of the additive will not have a significant

environmental impact. Copies of the environmental impact analysis report may be seen in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 10, 1978.

HOWARD R. ROBERTS,
Acting Director, Bureau of Foods.
[FR Doc. 78-7071 Filed 3-16-78; 8:45 am]

[4110-39]

National Institute of Education

PROGRAM OF RESEARCH GRANTS ON ORGANIZATIONAL PROCESSES IN EDUCATION

Closing Dates for Receipt of Applications

The National Institute of Education (NIE) hereby gives notice that, pursuant to the authority contained in section 405 of the General Education Provisions Act, as amended (20 U.S.C. 1221e), NIE is accepting applications for grants under the Program of Research Grants on Organizational Processes in Education. This notice is a reminder of dates already announced in FR Doc. 77-32166, published on November 7, 1977, at 42 FR 57992.

A. *Types of awards.* The program funds two types of grants. Small grants may be made for projects of up to 12 months' duration in amounts not to exceed \$7,500 in direct costs. Grants (other than small grants) may be made in any amount for projects of up to 3 years' duration.

B. *Application procedures.* Application for a grant (other than a small grant) requires a preliminary proposal, which is reviewed by NIE staff, scholars, and educators. NIE returns to the applicant an indication of the relative standing of the preliminary proposal among those received in the same cycle, and information on any major strengths or weaknesses found in the review. An applicant may submit a full proposal for a grant (other than a small grant) only after receiving the review of the preliminary proposal.

Application for a small grant requires only a full proposal, not a preliminary proposal.

In order to conduct its reviews, NIE requires 10 copies of each proposal submitted for review.

C. *Review cycles.* NIE will consider applications received at any time between the date of this notice and the end of the current fiscal year, September 30, 1978. (NIE intends to continue this program in future fiscal years, depending upon availability of funds and other factors. Dates for review cycles after September 30, 1978, will be published at a later time.)

Applications are reviewed in batches at 4-month intervals. The remaining

closing dates in this fiscal year for small grant and preliminary applications are: April 13, 1978; August 15, 1978.

The closing dates for full proposals from applicants who have previously received NIE comments on preliminary proposals are: April 27, 1978; August 15, 1978.

D. *Program information.* Interested persons may obtain a program announcement from the Research Staff, Group on School Capacity for Problem Solving, National Institute of Education, 1200 19th Street, NW. (Mail Stop 4), Washington, D.C. 20208 telephone 202-254-6090. The announcement includes copies of all rules governing the program, as well as information on availability of funds, expected number of awards, eligibility and review criteria, and instructions on how to apply. Persons interested in applying for research support under this program are strongly urged to obtain the program announcement. Written requests for the program announcement should be accompanied by a self-addressed mailing label.

E. *Estimated distribution of program funds.* This program has available approximately \$1.0 million for initial funding of new awards made in response to applications filed by fiscal year 1978 deadlines. Initial projections call for awarding 20-30 grants in fiscal year 1978. About 15 of these will be small grants. Approximately \$100,000 of the \$1.0 million is reserved for small grants.

The program will support only projects of the highest quality, whether or not the program's resources are exhausted. Further, nothing in this announcement commits NIE to award any specific amount. The actual total of funds awarded may change because of a need to reserve funds for continuation of projects begun in earlier years, for contract or in-house research, or because of budget or staffing restrictions.

F. *Applications sent by mail.* Applicants should address proposals to: National Institute of Education, Proposal Clearinghouse, Washington, D.C. 20208, Attention: Organizational Research. The outside of the package should indicate whether it contains a preliminary, small grant, or full proposal.

G. *Hand-delivered applications.* Hand-delivered applications must be brought to the Proposals Clearinghouse, Room 708, 1832 M Street NW., Washington, D.C. The Clearinghouse will accept hand-delivered applications daily between the hours of 9 a.m. and 4:30 p.m., Washington, D.C. time, except Saturdays, Sundays, and Federal holidays.

H. *Late applications.* To be considered in a particular review cycle, an application must reach the Clearing-

house by 4:30 p.m., Washington, D.C. time on the deadline date. The Clearinghouse closes promptly on deadline dates, and no other NIE office accepts application packages. Applications received after a deadline will not be entered in that review cycle, no matter when postmarked, so applicants should mail proposals early to ensure timely delivery. An application not received by 4:30 p.m. on a particular deadline date will be held for review in the next cycle, or returned if the applicant requests.

I. Applicable regulations. The regulations applicable to this program include the NIE General Provisions Regulations (45 CFR Part 1400) published in the FEDERAL REGISTER on November 4, 1974, at 39 FR 38992, and the final regulations for the Program of Research Grants on Organizational Processes in Education published in the FEDERAL REGISTER on November 22, 1977, at 42 FR 59847.

(Catalog of Federal Domestic Assistance Number 13.950, Educational Research and Development.)

Dated: March 13, 1978.

PATRICIA ALBJERG GRAHAM,
Director,
National Institute of Education.

[FR Doc. 78-7152 Filed 3-16-78; 8:45 am]

[4110-08]

National Institutes of Health REVIEW OF CONTRACT PROPOSALS

Meetings

Pursuant to Public Law 92-463, notice is hereby given of the meetings of committees advisory to the National Cancer Institute.

These meetings will be open to the public to discuss administrative details or other issues relating to committee business as indicated in the notice. Attendance by the public will be limited to space available.

These meetings will be closed to the public as indicated below in accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of Public Law 92-463, for the review, discussion and evaluation of individual contract proposals, as indicated. These proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposals.

Mrs. Marjorie F. Early, Committee Management Officer, NCI, Building 31, Room 4B43, National Institutes of Health, Bethesda, Md. 20014, 301-496-5708, will furnish summaries of the meetings and rosters of committee members, upon request. Other information pertaining to the meeting can

be obtained from the Executive Secretary indicated. Meetings will be held at the National Institutes of Health, 9000 Rockville Pike, Bethesda, Md. 20014, unless otherwise stated.

Name of committee: Carcinogenesis Program Scientific Review Committee.

Dates: April 3-4, 1978; 8:30 a.m.

Place: Building 31C, Conference Room 9, National Institutes of Health.

Times: Open April 3, 8:30 a.m.-9 a.m., April 4, 8:30 a.m.-9 a.m. Closed April 3, 9 a.m.-5 p.m., April 4, 9 a.m.-adjournment.

Closure reason: To review research contract proposals.

Executive secretary: Dr. Carl E. Smith, Landow Building, Room 8C37, National Institutes of Health, 301-496-1071. (Catalog of Federal Domestic Assistance number 13.393, National Institutes of Health.)

Name of committee: Developmental Therapeutics Committee.

Dates: April 4, 1978; 9 a.m.-adjournment.

Place: Blair Building, Room 110, 8300 Colesville Road, Silver Spring, Md. 20910.

Times: Open April 4, 9 a.m.-9:30 a.m. Closed April 4, 9:30 a.m.-adjournment.

Closure reason: To review research contract proposals.

Executive Secretary: Dr. J. A. R. Mead, Blair Building, Room 5A03, National Institutes of Health, 301-427-7263. (Catalog of Federal Domestic Assistance number 13.395, National Institutes of Health.)

Name of committee: Committee on Cytology Automation.

Dates: April 6-7, 1978, 8:30 a.m.

Place: Building 31C, Conference Room 8, National Institutes of Health.

Times: Open April 6, 8:30 a.m.-9:30 p.m. Closed April 6, 9:30 a.m.-5 p.m., April 7, 8:30 a.m.-adjournment.

Closure reason: To review research contract proposals.

Executive Secretary: Dr. Bill Bunnag, Building 10, Room 1A21, National Institutes of Health, 301-496-5282. (Catalog of Federal Domestic Assistance Number 13.394, National Institutes of Health.)

Name of committee: Committee on Cancer Immunodiagnosis.

Dates: April 18, 1978, 1 p.m.-adjournment.

Place: Building 10, Room 4B14, National Institutes of Health.

Times: Open April 18, 1 p.m.-1:30 p.m. Closed April 18, 1:30 a.m.-adjournment.

Closure reason: To review research contract proposals.

Executive Secretary: Mrs. Judith M. Whalen, Building 10, Room 4B17, National Institutes of Health, 301-496-1791. (Catalog of Federal Domestic Assistance Number 13.394, National Institutes of Health.)

Name of committee: Virus Cancer Program Scientific Review Committee.

Dates: April 24-26, 1978, 9 a.m.

Place: Landow Building, Room 4C18, 7910 Woodmont Building, Bethesda, Md. 20014.

Times: Open April 24, 9 a.m.-9:30 p.m. Closed April 24, 9:30 a.m.-5 p.m., April 25, 9 a.m.-5 p.m., April 26, 9 a.m.-adjournment.

Closure reason: To review research contract proposals.

Executive Secretary: Dr. Maurice L. Guss, Landow Building, Room 9A10, National Institutes of Health, 301-496-4533. (Catalog of Federal Domestic Assistance

Number 13.393, National Institutes of Health.)

Dated: March 7, 1978.

SUZANNE L. FREMEAUX,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 78-6703 Filed 3-16-78; 8:45 am]

[4110-08]

CARCINOGENESIS PROGRAM SCIENTIFIC REVIEW COMMITTEE

Renewal

The Director, National Institutes of Health, announces the renewal on March 2, 1978, of the Carcinogenesis Program Scientific Review Committee, under the authority of section 410(a)(3) of the Public Health Service Act (42 U.S.C. 286d). Such advisory committees shall be governed by the provisions of the Federal Advisory Committee Act, as amended (Pub. L. 92-463) setting forth standards governing the establishment and use of advisory committees.

This committee provides to the Director, NCI, and the Director, Division of Cancer Cause and Prevention, advice concerning scientific merit of proposals for contracts submitted to the carcinogenesis program of the National Cancer Institute. The committee will terminate March 2, 1980, unless renewed by appropriate action as authorized by law.

Dated: March 8, 1978.

DONALD S. FREDRICKSON,
Director,
National Institutes of Health.

[FR Doc. 78-6713 Filed 3-16-78; 8:45 am]

[4110-08]

CANCER CONTROL COMMUNITY ACTIVITIES REVIEW COMMITTEE

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Cancer Control Community Activities Review Committee, National Cancer Institute, April 27-29, 1978, Building 31, Conference Room 4, 9000 Rockville Pike, Bethesda, Md. 20014. Except as noted below, this meeting will be open to the public on April 27, 1978, from 8:30 a.m. to 5 p.m. for administrative details and to review contracts with the New Mexico cancer control program and the Metropolitan Detroit cancer control program for implementation of community-based cancer control programs. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in section 552b(c)(6), Title 5 United States Code, and section 10(d) of Pub. L. 92-463, the meeting will be