(HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Elke Jensen, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3109.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 6B4506) has been filed by Henkel Corp., 300 Brookside Ave., Ambler, PA 19002. The petition proposes to amend the food additive regulations in part 176 Indirect Food Additives: Paper and Paperboard Components (21 CFR part 176) to provide for the safe use of α-sulfo-ω-(dodecyloxy)poly(oxyethylene), sodium salt as an emulsifier in the production of acrylic and vinyl acetate polymer coatings for paper and paperboard. The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before (insert date 30 days after date of publication in the Federal Register), submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: June 20, 1996.

George H. Pauli,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–17233 Filed 7–5–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93F–0402]

Lonza, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 4B4405) proposing that the food additive regulations be amended to provide for the safe use of decylisononyldimethyl ammonium chloride as a slimicide in the manufacture of paper and paperboard intended to contact food.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of November 17, 1993 (58 FR 60665), FDA announced that a food additive petition (FAP 4B4405) had been filed by Lonza, Inc., c/o Delta Analytical Corp., 7910 Woodmont Ave., Bethesda, MD 20814 (currently c/o Lewis & Harrison, 122 C St. NW., suite 740, Washington, DC 20001). The petition proposed to amend the food additive regulations to provide for the safe use of decylisononyldimethyl ammonium chloride as a slimicide in the manufacture of paper and paperboard intended to contact food. Lonza, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: June 25, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–17234 Filed 7–5–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96M–0218]

Adeza Biomedical Corp.; Premarket Approval of Fetal Fibronectin Enzyme Immunoassay Kit

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Adeza Biomedical Corp., Sunnyvale, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Fetal Fibronectin Enzyme Immunoassay Kit. After reviewing the recommendation of the Clinical Chemistry and Clinical Toxicology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 29, 1995, of the approval of the application.

DATES: Petitions for administrative review by August 7, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Cornelia B. Rooks, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243.

SUPPLEMENTARY INFORMATION: On October 31, 1994, Adeza Biomedical Corp., Sunnyvale, CA 94089, submitted to CDRH an application for premarket approval of Fetal Fibronectin Enzyme Immunoassay Kit. The device is to be used as an aid in assessing the risk of preterm delivery in ≤ 7 days or ≤ 14 days from the time of sample collection in pregnant women with signs and symptoms of early preterm labor, intact amniotic membranes, and minimal cervical dilatation (< 3 centimeters), sampled between 24 weeks, 0 days and 34 weeks, 6 days gestation.

The negative predictive values of 99.5 percent and 99.2 percent, for delivery in ≤ 7 and ≤ 14 days respectively, make it highly likely that delivery will not occur in these timeframes. In addition, although the positive predictive values were found to be 12.7 percent and 16.7 percent for delivery in ≤ 7 and ≤ 14 days, respectively, this represents an approximate 4-fold increase over the reliability of predicting delivery given no test information.

On April 6, 1995, the Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On September 29, 1995, CDRH approved the application by a letter to

the applicant from the Director of the office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 7, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 21, 1996.

Joesph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–17235 Filed 7–5–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the President's Cancer Panel.

The meeting will be open to the public as indicated below, with attendance by the public 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.

The meeting will be closed in accordance with the provisions set forth in sec. 552b(c)(9), Title 5, U.S.C. for discussion of future meetings and preparation of the annual report to the President. These discussions could disclose information, the premature disclosure of which would be likely to significantly frustrate implementation of proposed action the Panel may plan to take.

Carole Frank, the Committee Management Officer, National Cancer Institute, Executive Plaza North, Room 630M, 6130 Executive Blvd., MSC 7405, Bethesda, MD 20891–7405 (301–496–5708) will provide a summary of the meeting and the roster of committee members upon request. Other information pertaining to the meetings may be obtained from the contact person indicated below.

Committee Name: President's Cancer Panel.

Date: July 29–30, 1996.

Place: Fred Hutchinson Cancer Center, Stuart Auditorium, First Hill, 1124 Columbia Street, Seattle, WA 98104.

Closed: July 29, 1996—7 p.m. to 10 p.m.

Agenda: Planning session to discuss future meetings and preparation of the mandatory annual report of the Chairman to the President.

Open: July 30, 1996—8:30 a.m. to 5:00 p.m.

Agenda: Managed Care's Role in the War on Cancer. Where are we today? Existing problems for cutting edge clinical research in today's environment.

Contact Person: Dr. Maureen O. Wilson, Executive Secretary, National Cancer Institute, NIH, Building 31, Room 4B43, Bethesda, MD 20892, (301) 496–1148.

(Catalog of Federal Domestic Assistance Program Numbers: 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.)

Dated: July 1, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–17209 Filed 7–5–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Allergy and Infectious Diseases; 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 National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meeting:

Name of SEP: Unsolicited AIDS Related Career Award, Conference and Supplement Applications

Date: July 26, 1996

Time: 8:30 a.m.

Place: Doubletree Hotel, Rockville Room, 1750 Rockville Pike, Rockville, MD 20852, (301) 468–1100.

Contact Person: Dr. Paula Strickland, Scientific Review Adm., 6003 Executive Boulevard, Solar Bldg., Room 4C02, Bethesda, MD 20892–7610, (301) 402–0643.

Purpose/Agenda: To evaluate grant applications.

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

(Catalog of Federal Domestic Assistance Programs Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health.)

Dated: July 1, 1996.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 96–17210 Filed 7–5–96; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Environmental Health Sciences; Notice of a 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 National Institute of Environmental Health Sciences Special Emphasis Panel (SEP) meeting:

Name of SEP: The Use of Transgenic Model Systems in Molecular Toxicology.