(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