''Effective for the treatment of clinical and subclinical mastitis caused by *Staphylococcus* species such as *Staphylococcus aureus*, and *Streptococcus* species such as *Streptococcus agalactiae, Streptococcus uberis*.''

This would eliminate the need in a clinical study to enroll 100 clinical cases per pathogen per treatment group. The study would need to demonstrate adequate power to detect an overall treatment-cure rate above that of the untreated control group. This would take into account spontaneous cure rates.

CVM considered the above comments and has revised the guidance document accordingly in light of CVM's position on this issue. CVM believes that under current regulations, use of positive control studies are permitted, however, CVM is trying to determine what constitutes ''efficacy threshold.'' CVM would still require a negative controlled study in order to separate the spontaneous cure rate from the cure rate attributable to the drug. If a sponsor is considering a positively controlled study, the sponsor should provide a basis for the need to have such a study, and thus be exempted from this standard. It should be discussed with and approved by CVM prior to the study. The design of the positively controlled study needs to be such that depending on the spontaneous cure rates, the study would detect an overall cure rate for the treatment group of 65 to 70 percent per pathogen.

6. Minimum Inhibitory Concentration/ Pharmacokinetic Data (MIC/PK Data)

The comment stated that utilization of MIC/PK data for intramammary/mastitis products is still in the scientific discovery stage. The basis for correlating milk residue/efficacy/MIC data to draw a reasonable scientific conclusion is unavailable.

CVM agrees with the above comment, however, the use of MIC/PK data for intramammary products should be addressed when CVM considers the flexible labeling issues and should not be addressed in this current anti-infective bovine mastitis drug guidance document.

7. Non-lactating Treatment and Prevention Products

The comment stated that separate studies would be necessary to obtain a treatment and prevention label claim.

CVM agrees with the comment and has revised the draft guidance to indicate that separate studies would be necessary to obtain a treatment and prevention label claim for use in the dry cow. For the prevention claim, the sponsor would need to establish, through a negative controlled group, the new infection rate (estimates are approximately 2 to 3 percent) and demonstrate at least a 50 percent reduction in the rate of new infections. The criteria for defining a cure is as for clinical mastitis in the lactating cow, i.e., no clinical signs and negative culture at time of freshening.

Guidelines are generally issued under §§ 10.85(a) and 10.90(b) (21 CFR 10.85(a) and 10.90(b)). The agency is now in the process of revising §§ 10.85(a) and 10.90(b). Therefore, this guidance document is not being issued under §§ 10.85(a) and 10.90(b), and it does not bind the agency, and does not create or confer any rights, privileges, or benefits for or on any person. However, it represents the agency's current thinking on this issue. A person may follow the guidance document or may choose to follow alternative procedures or practices. If a person chooses to use alternate procedures or practices, that person may wish to discuss the matter with FDA/CVM to prevent an expenditure of money and effort on activities that may later be determined to be unacceptable. When a guidance document states a requirement imposed by statute or regulation, however, the requirement is law and its force and effect are not changed in any way by virtue of its inclusion in the guidance document.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the document. 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. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 23, 1996.

William K. Hubbard,

*Association Commissioner for Policy Coordination.*

[FR Doc. 96–10485 Filed 4–26–96; 8:45 am]

BILLING CODE 4160–01–F

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**[Docket No. 93F-0102]**

## Ciba-Geigy Corp.; 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 3B4361), filed by Ciba-Geigy Corp., proposing that the food additive regulations be amended to provide for safe use of the reaction product of 4,4′-isopropylidenediphenol-epichlorohydrin resin, 4,4′-isopropylidenediphenol bis[(2-glycidyloxy-3-n-butoxy)-1-propyl ether], and 4,4′-isopropylidenediphenol as a component of coatings for food-contact use.

**FOR FURTHER INFORMATION CONTACT:** Julius Smith, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

**SUPPLEMENTARY INFORMATION:** In a notice published in the Federal Register of April 19, 1993 (58 FR 21173), FDA announced that a food additive petition (FAP 3B4361) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532–2188. The petition proposed to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) to provide for the safe use of the reaction product of 4,4′-isopropylidenediphenol-epichlorohydrin resin, 4,4′-isopropylidenediphenol bis[(2-glycidyloxy-3-n-butoxy)-1-propyl ether], and 4,4′-isopropylidenediphenol as a component of coatings for food-contact use. Ciba-Geigy Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7)

Dated: April 10, 1996.

Alan M. Rulis,

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

[FR Doc. 96–10547 Filed 4–26–96; 8:45 am]

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## 1996 Gene Therapy Conference: Development and Evaluation of Phase I Products and Workshop on Vector Development; Notice of Public Conference

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

**ACTION:** Notice of public conference.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public conference entitled ''1996 Gene Therapy Conference: Development and Evaluation of Phase I Products and Workshop on Vector Development.'' The objective of this conference is to educate investigators on the

investigational new drug (IND) process, points-to-consider documents, resources available from the National Institutes of Health (NIH) to bring gene therapy from the research laboratory to clinical trials, and to conduct a series of workshops on various issues concerning the development, production, and use of viral vectors for gene therapy. FDA believes that the conference will benefit interested parties, including industry, NIH, and FDA, involved in this rapidly advancing and changing field of gene therapy.

**DATES:** The public conference will be held on Thursday and Friday, July 11 and 12, 1996, 8 a.m. to 5 p.m. Preregistration is requested by June 28, 1996. Registration will be held on both days from 7:30 a.m. to 8 a.m.

**ADDRESSES:** The public conference will be held at NIH, Bldg. 45, Natcher Auditorium, 9000 Rockville Pike, Bethesda, MD. There is no registration fee. For a complete description of the conference, agendas, speakers, and session chairs check the FDA Biologics Home Page at http://www.fda.gov/cber/cberftp.html. The home page will be updated as the conference gets closer.

**FOR FURTHER INFORMATION CONTACT:**

Regarding information on registration: Margaret Fanning, NCI–FCRDC, P.O. Box B, Frederick, MD 21702–1201, 301–846–5865, or FAX 301–846–5866.

Regarding information on the conference agenda: Bette A. Goldman, Center for Biologics Evaluation and Research (HFM–500), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–2860.

**SUPPLEMENTARY INFORMATION:** Gene therapy is a dynamic and rapidly advancing field of scientific study. The purpose of this conference is twofold. On July 11, 1996, FDA hopes to provide the gene therapy community with an education and understanding of the IND review process. Many academic investigators and researchers involved in the research and development of gene therapies are not familiar with the regulatory process for the review of IND's. This lack of knowledge of the IND process may decrease the efficiency of pre-IND meetings and increase the review burden on FDA staff. In order to address this problem, the conference will include a description of the IND process, the use of ''points-to-consider'' and guideline documents, and resources available from NIH to bring gene therapy from the research laboratory to clinical trials. On July 12, 1996, the conference will serve as an opportunity for FDA to hear concerns, issues, and ideas from the gene therapy community. There will be presentations of the available scientific data from various groups, followed by discussions, in order to improve understanding of scientific issues that are the foundation of regulatory guidelines. Breakout sessions will address the following: Adenoviral vectors, ancillary products, facilities and manufacturing, information on getting started in gene therapy development, retroviral vectors, pharmacology, toxicology, and the development of new vector systems.

The information obtained from this conference may assist in the development of future scientific and regulatory policy or guidance.

Dated: April 19, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96–10484 Filed 4–26–96; 8:45 am]

**BILLING CODE 4160–01–F**

## Health Resources and Services Administration

### Program Announcement and Proposed Project Requirements and Review Criteria for Cooperative Agreements for Partnerships for Health Professions Education for Fiscal Year 1996

The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year (FY) 1996 Cooperative Agreements for Partnerships for Health Professions Education. This model/demonstration program will be jointly funded under sections 738(b) (Minority Faculty Fellowship Program), 739 (Centers of Excellence in Minority Health Professions Education), and 740 (Health Careers Opportunity Program) of the Public Health Service Act, as amended by the Health Professions Education Extension Amendments of 1992, Pub. L. 102–408, dated October 13, 1992. The goal of this program is to establish and test a comprehensive model program in a geographically defined area (e.g., region, state, metropolitan or rural area), that incorporates a variety of educational and community-based entities in a formal continuum of activities to increase the number and quality of: (1) Minority and disadvantaged health professionals to provide health services to underserved populations and (2) minority faculty serving in health professions schools. No comprehensive model currently exists.

Rationale

The rationale for conducting this model project is to:

1. Test the feasibility and effectiveness of executing a comprehensive program in a defined geographic area, which encompasses a dynamic coordinated educational continuum designed to increase the number and quality of minority/disadvantaged health professionals and minority faculty for health professions schools. This program includes formal linkages among several community-based entities and educational institutions.

2. Compare performance outputs of a comprehensive approach versus the output of several independent projects operating in a defined geographic area as is currently practiced.

3. Assess the cost effectiveness of a comprehensive model versus a multiple independent projects approach (testing the hypothesis that approximately one third of the costs for personnel and overhead expenditures would be saved through a comprehensive administrative infrastructure).

4. Determine the potential for several community and educational entities forming a unified, effective, multi-dimensional, comprehensive educational continuum under the umbrella of a single lead institution.

5. Test the relative soundness of a cooperative comprehensive approach versus that of several projects acting independently. This would facilitate tracking, monitoring and retaining targeted individuals through the educational pathway to become health professionals and/or faculty in health professions schools.

This program announcement is subject to reauthorization of the legislative authorities and to the appropriation of funds. Applicants are advised that this program announcement is a contingency action being taken to assure that should authority and funds become available for this purpose, they can be awarded in a timely fashion consistent with the needs of the program as well as to provide for even distribution of funds throughout the fiscal year. At this time, given a continuing resolution and the absence of FY 1996 appropriations for title VII programs, the amount of available funding for this specific cooperative agreement cannot be estimated.

*Purpose*

The purposes of this program are to: (1) Assist schools in supporting programs of excellence in health