''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CVM agrees with the comment and has revised the draft guidance to indicate that separate studies would be necessary to obtain a treatment and prevention label claim for use in the dry cow.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]

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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