Resettlement Program to submit an annual report with a count of the number of refugees receiving cash and medical assistance or social services who were initial resettled in another State. The State does this by counting the number of refugees with social security numbers indicating residence in another State at the time of arrival in the U.S. (The first three digits of the social security number indicate the State of residence of the applicant.)

Data submitted by the States are compiled and analyzed by the ORR statistician, who then prepares a summary report which is included in ORR's annual Report to Congress. The primary use of the data is to quantify and analyze refugee secondary migration among the 50 States. ORR uses these data to adjust its refugee arrival totals for each State in order to calculate the social services allocation formula.

Respondents: State Governments.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–11	50	1	.434	217

Estimated Total Annual Burden Hours: 217.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by title.

In addition, requests for copies may be made and comments forwarded to the Reports Clearance Officer over the Internet by sending a message to rkatson@acf.dhhs.gov. Internet messages must be submitted as an ASCII file without special characters or encryption.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 22, 1996.

Roberta Katson,

Director, Division of Information Resource Management Services.

[FR Doc. 96–10532 Filed 4–26–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 93D–0025]

Target Animal Safety and Drug Effectiveness Studies for Anti-Microbial Bovine Mastitis Products; Guidance Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the revised guidance document entitled ''Target Animal Safety and Drug Effectiveness Studies for Anti-Microbial Bovine Mastitis Products (Lactating and Non-lactating Cow Products)'' prepared by the Center for Veterinary Medicine (CVM). This guidance document serves to interpret statutory and regulatory requirements and outlines general procedures for conducting evaluations for anti-microbials being considered for approval.

DATES: Written comments on the guidance document may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the revised guidance document entitled, ''Target Animal Safety and Drug Effectiveness Studies for Anti-Microbial Bovine Mastitis Products'' to the Communications and Education Branch (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and received comments may be seen at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1659.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of the revised guidance document entitled ''Target Animal Safety and Drug Effectiveness Studies for Anti-Microbial Bovine Mastitis Products (Lactating and Non-lactating Cow Products)'' prepared by CVM. The guidance document is intended to be used by the pharmaceutical industry for information regarding the types of data that will demonstrate that an anti-microbial mastitis product is safe and effective for both lactating and non-lactating cows. In the Federal Register of February 10, 1993 (58 FR 7893), FDA issued a notice of availability of the CVM draft guideline entitled ''Guideline for Target Animal and Human Food Safety, Drug Efficacy, Environmental and Manufacturing Studies for Anti-Infective Bovine Mastitis Products.'' Comments by interested persons were requested.

In response to the February 19, 1993, notice, the Animal Health Institute (AHI) notified CVM, by letter dated June 28, 1993, of its intent to form a working group, the Dairy Industry Consortium (DIC), to address the draft CVM guideline ''Guideline for Target Animal and Human Food Safety, Drug Efficacy, Environmental and Manufacturing

Studies for Anti-Infective Bovine Mastitis Products.'' Comments and alternative proposals from the AHI/DIC were forwarded to FDA/CVM in a letter dated May 24, 1994.

Because AHI/DIC put forth extensive complex scientific comments, CVM agreed to participate in a workshop to further discuss and clarify the AHI/DIC comments. FDA/CVM representatives participated in the workshop, which was held on June 2, 1994, in Alexandria, VA. The objective of this workshop was to hold a public meeting to allow for the discussion of AHI/DIC comments. The draft guideline was discussed at the workshop. In a letter dated July 14, 1994, AHI circulated minutes of the workshop to all attendees. In a letter dated August 11, 1994, CVM provided comments on the July 14, 1994, AHI minutes of the workshop. As a result of CVM's comments, a subsequent meeting was held on September 23, 1994, between representatives of FDA/CVM and AHI/DIC to clarify scientific points made in the minutes of the workshop.

No other comments on that draft guideline were received by the agency. The comments on the draft guideline from AHI/DIC are discussed below:

1. General Issues

It was recommended that the final guidance document encompass only the efficacy and target animal safety of anti-infective bovine mastitis products. The draft guideline provided a discussion on other components of the new animal drug application (NADA).

CVM concurs with this comment. The guidance document will mainly address efficacy and target animal safety. Other components of the NADA will be addressed under separate guidance documents (e.g., environmental assessment and manufacturing).

2. Enrollment in Study for Clinical Infectious Mastitis

It was recommended that the enrollment of a clinical mastitis case in an efficacy study include the presence of abnormal milk and/or udder clinical signs at enrollment as the primary element. The presence of microorganisms should be strictly secondary. The experimental unit should be the lactating dairy cow with clinical mastitis (abnormal milk and/or udder clinical signs). For future clinical studies, only cows with a single quarter with clinical mastitis should be enrolled. CVM should use this single quarter data base to infer efficacy to all cows with mastitis in one or more quarters. The diagnosis of clinical mastitis should be the only signalment needed for enrollment in the study. Prior to treatment, single samples for microbiologic and somatic cell count (SCC) assessment should be obtained. Only the single affected quarter will be treated. Any cow developing mastitis in additional quarters during her enrollment should be dropped from the study and not considered failure. Cows requiring and/or receiving treatment in an additional mastitic quarter should be excluded from consideration in the study. Only clinical cases of mastitis in which a mastitis pathogen is isolated in the pretreatment sample should be used to calculate cure rate. It should be necessary to submit to CVM the pre and posttreatment bacteriological culture data from those cows that were initially enrolled in the study but subsequently cultured negative on the pretreatment sample.

CVM agrees with these comments. The guidance document has been revised to reflect these comments.

3. Definition of Cure

It was recommended that the definition of cure should include two parts, a clinical portion and a bacteriological portion. The current definition of cure lacks the clinical assessment. The cure should be assessed between 14 and 28 days posttreatment based on the negative control study design. Clinically, a cured quarter should have normal milk and no clinical signs of mastitis in that quarter. Microbiologically, the mastitis pathogen isolated in the pretreatment sample should be absent from two posttreatment test samples. A minimum of two single microbiology test samples should be obtained at least 5 days apart during the assessment period (14 to 28 days posttreatment). Two single SCC samples should be obtained at the same time. SCC should not be used in the determination of cure for the individual cow. SCC results should only be used as a check of the numerical trend between the means of SCC for ''cured'' and ''not-cured'' cows within each treatment group to determine if other studies are needed for inflammation and safety.

CVM agrees with the proposed definition of cure. The guidance document has been revised to reflect these comments.

4. Enrollment in Study for Subclinical Mastitis

It was recommended that all new anti-infective products for mastitis in the lactating dairy cow must show efficacy for clinical mastitis. No new product should be licensed with subclinical data as in the old guidelines. CVM should consider alternative approaches with adequate justification. To obtain a subclinical indication, additional subclinical data should be required. With acceptable clinical mastitis efficacy results, the subsequent subclinical mastitis study should require that the new therapy demonstrate efficacy but at a lower probability level ($p<0.10$). This should require fewer cows to be necessary for the subclinical study because elimination of the pretreatment pathogen is required in the clinical study. Subclinical trial(s) should select cows with a positive quarter, thus fewer cows may be needed. The subclinical study should be a randomized study. Prior to treatment, two single microbiology and SCC samples should be obtained at a 24-hour interval. At 14 to 28 days posttreatment, two single microbiologic and SCC samples should be obtained at least 5 days apart. In the subclinical study, only one quarter from any cow would be treated. For cows infected in multiple quarters, the quarter to be treated would be randomly selected. The other quarters would not be treated. If additional quarters of clinical mastitis requires additional treatment, the cow would be ineligible for inclusion in the study. Definition of cure for the subclinical study constitutes the elimination of the bacteria isolated in both pretreatment samples. SCC results should be used similarly in subclinical studies as for clinical studies to detect changes and perhaps indicate possible safety problems. Products with acceptable efficacy data from both clinical and subclinical studies should receive the following indication: ''Effective for the treatment of clinical and subclinical mastitis caused by* * *''.

CVM agrees with these comments. The guidance document has been revised to incorporate these comments.

5. Design of Field Studies

It was recommended that clinical efficacy studies would be multilocation/multiherd studies. CVM should eliminate the requirement that a study herd must have a 20 percent incidence of clinical mastitis to participate. Herds participating in a clinical study should have a sufficient number of clinical mastitis cases to fill an adequate number of blocks. Obtaining an adequate number of pathogens may involve multiple locations to fulfill the number needed for each block within the study. In the clinical study, the distribution of mastitis pathogens from the study should be utilized to determine the label efficacy statement. An example for an effective antibiotic for staph and strep mastitis pathogens would be:

''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

[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]

BILLING CODE 4160–01–F

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