been altered to provide that notification shall be furnished to the Plant Protection and Quarantine Officer at the port of arrival. This change has been made because such officer will be responsible for the handling of the proposed shipment. Therefore, it appears reasonable to notify such Plant Protection and Quarantine Officer instead of the Deputy Administrator, Veterinary Services. Additionally, because of the aforementioned change, notification must only be made prior to the transiting rather than one day prior to entry. The one day period had been proposed to allow the Deputy Administrator time to contact the PPQ officer at the port of entry. However, since notice is to be furnished directly to the PPQ officer at the port of entry, notification must only be made prior to transiting.

Accordingly, new § 94.15 of the regulations (9 CFR 94.15) is added to read:

§ 94.15 Animal products and materials; movement and handling.

Any animal product or material which would be eligible for entry into the United States, as specified in the regulations in this part, may transit through the United States for immediate export if the following conditions are met:

(a) Notification of the transiting of such animal product or material must be made by the importer to the Plant Protection and Quarantine Officer at the United States port of arrival prior to such transiting, and

(b) The animal product or material transited shall be contained in a sealed, leakproof carrier or container which shall remain sealed while aboard the transporting carrier or other means of conveyance, or if the container or carrier in which such animal product or material is transported is offloaded in the United States for reshipment, it shall remain sealed at all times.

(Sec. 306, 46 Stat. 689, as amended; sec. 2, 32 Stat. 792, as amended (19 U.S.C. 1306; 21 U.S.C. 111); 37 FR 28464, 28477; 38 FR 19141.)

Insofar as the amendment relieves certain restrictions presently imposed but no longer deemed necessary to prevent the spread of disease, and in order to avoid unnecessary interference with foreign commerce it should be made effective immediately to be of maximum benefit to affected persons.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, good cause is found for making this amendment effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 30th day of January 1978.

NOTE.—The Animal and Plant Health Inspection Service has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

J. K. ATWELL,
Acting Deputy Administrator,
Veterinary Services.

[FR Doc. 78-2925 Filed 2-2-78; 8:45 am]

[4810-22]

Title 19—Customs Duties

CHAPTER I—U.S. CUSTOMS SERVICE

[T.D. 78-36]

PART 162—INSPECTION, SEARCH, AND SEIZURE

Filing of Petitions for Relief

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This rule expands a district director's authority to grant an extension of time for filing a petition for relief from a fine, penalty, or forfeiture arising under the Customs or navigation laws. The regulations prescribe a 60-day period for ng a petition, with limited authority for a district director to extend the period if the person who is liable for a fine or penalty, or who has an interest in the property subject to forfeiture, is abroad or was abroad for 30 days or more of the filing period. By permitting the district director to extend the filing period for other good reasons of which he is aware, this rule continues the Customs policy of delegating decisionmaking authority to the level at which it can be most effectively exercised.

EFFECTIVE DATE: February 3, 1978.

FOR FURTHER INFORMATION CONTACT:

Marilyn Morrison, Entry Procedures and Penalties Division, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229, 202-566-5746.

SUPPLEMENTARY INFORMATION:

BACKGROUND

In pertinent part, section 162.32(a) of the Customs Regulations (19 CFR 162.32(a)) requires a person who is liable for a fine or penalty, or who has an interest in property subject to forfeiture, for any violation of the Customs or navigation laws to file a petition for relief within 60 days from the date that the notice of penalty is mailed. However, a district director may grant an extension of time for filing the petition if the person is outside the United States or was outside the United States for 30 days or more during the filing period. If a petition is not filed within the 60-day period, the district director must refer the case to the United States attorney for the start of collection proceedings unless the Commissioner of Customs authorizes other action.

Because of the present limitations on a district director's authority to grant an extension of time for filing a petition, a request for such an extension usually must be referred to the Commissioner of Customs for decision, even though the district director is often in the best position to determine whether an extension of time is justified. Accordingly, section 162.32(a) of the Customs Regulations is being amended to increase the authority of a district director with respect to extensions of the filing period for petitions for relief. This amendment, which specifies additional situations in which a district director may act on a request for an extension of the filing period, does not affect the present authority of the Commissioner to grant an extension or to take any other action on a case.

DRAFTING INFORMATION

The principal author of the document is William G. Rosoff, Regulations and Legal Publications Division of the Office of Regulations and Rulings, United States Customs Service. However, personnel from other offices of the Customs Service participated in developing the document, both on matters of substance and style.

AMENDMENT TO THE REGULATIONS

This amendment is considered to be exempt from the notice requirements of 5 U.S.C. 553 because it solely concerns agency procedure.

Accordingly, section 162.32(a) of the Customs Regulations (19 CFR 162.32(a)) is amended to read as follows:

§ 162.32 Where petition for relief not filed.

(a) *Fines, penalties, and forfeitures.* If the person who is liable for a fine or penalty, or who has an interest in property subject to forfeiture, for any violation of the Customs or navigation laws fails to petition for relief in accordance with Part 171 of this chapter, or to pay or to arrange to pay the fine or penalty within 60 days from the date of mailing of the notice of violation as provided in section 162.31, the district director shall immediately refer the case to the U.S. attorney for judicial action unless the Commissioner of Customs expressly authorizes other action with respect to the case. However, if there is at least 1 year before the statute of limitations may be asserted as a defense, a district director may extend the time for filing a petition, upon the request of the person who is liable for a fine or penalty, or who has an interest in property subject to forfeiture, in the following situations:

1. The person is seriously ill or is otherwise incapacitated and is unable to prepare or to assist in the preparation of a petition.

2. The person is absent from the United States or was absent from the United States for 30 days or more during the 60-day filing period.

3. Necessary evidence or a necessary witness is not available through no fault of the person.

4. The case involves a complex legal or factual problem other than a classification, appraisement, or similar issue. Examples of the type of problem intended to be covered by this category are the need to examine voluminous records to learn the facts on which to base a petition or the need to determine legal responsiblities in a case involving numerous parties or numerous violations.

5. The existence of unusual circumstances, such as a fire or other disaster, affecting the business of the person which requires the full attention of that person in order to overcome the effects of the unusual circumstances.

6. Any other situation in which the district director determines that an extension of time for filing a petition is justified.

* * * * *

(R.S. 251, as amended; sec. 624, 46 Stat. 759 (19 U.S.C. 66, 1624).)

G. R. DICKERSON,
Acting Commissioner of Customs.

Approved: January 18, 1978.

BETTE B. ANDERSON,
Under Secretary of the Treasury.

[FR Doc. 78-3013 Filed 2-2-78; 8:45 am]

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

[Docket No. 76N-0366]

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

Postponement of Closing Date

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: The Commissioner of Food and Drugs is postponing the closing date for the provisi listing of lead acetate. The new closing date is February 28, 1978.

EFFECTIVE DATE: January 31, 1978.

FOR FURTHER INFORMATION CONTACT:

Gerad L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street, SW., Washington, D.C. 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: The current closing date of January 31, 1978 for the provisional listing of lead acetate was established by regulation published in the FEDERAL REGISTER of November 4, 1977 (42 FR 57686). In the FEDERAL REGISTER of December 13, 1977 (42 FR 62497), the Commissioner proposed to postpone the closing date for lead acetate until April 30, 1979 to allow time for the petitioner for listing of the color additive to develop additional data on the likelihood of lead acetate being absorbed through the skin. On January 20, 1978, a comment was received on that proposal from the Environmental Defense Fund (EDF) which opposed the proposal. On January 27, 1978, a response to the EDF comment was received from Combe, Inc., a manufacturer of hair coloring preparations containing lead acetate.

The closing date for the provisional listing of lead acetate is being postponed to permit time to evaluate fully the EDF comment, Combe's response, and other pertinent scientific material. The Commissioner will issue a notice in the FEDERAL REGISTER on or before February 28, 1978, which will contain his conclusions about continued provisional listing for lead acetate.

The Commissioner concludes that notice and public procedure on this regulation are impracticable and contrary to the public interest and that good cause exists for issuing this postponement as a final order. This regulation, to be effective on January 31, 1978, will permit the uninterrupted use of the affected color additive until further action is taken. Therefore, in accordance with 5 U.S.C. 553(b) and (d) (1) and (3), this postponement is issued as a final regulation and is being made effective on January 31, 1978.

Therefore, under the transitional provisions of the Color Additive Amendments of 1960 to the Federal Food, Drug, and Cosmetic Act (Title II, Pub. L. 86-618; sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner (21 CFR 5.1), Part 81 is amended in § 81.1 Provisional lists of color additives, by revising the entry for the closing date for the color additive lead acetate listed in paragraph (g) to read "February 28, 1978."

Effective date: January 31, 1978.

(Sec. 203, 74 Stat. 404-407 (21 U.S.C. note).)

Dated: January 31, 1978.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc. 78-3103 Filed 2-1-78; 11:15 am]

[4110-03]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 76P-0500]

PART 135—FROZEN DESSERTS

Standards of Identity for Frozen Desserts; Confirmation of Effective Date of One Provision, and Revocation of Certain Stayed Provisions

AGENCY: Food and Drug Administration.

ACTION: Final rule and revocation of stayed regulations.

SUMMARY: This document confirms thevision for reduction in milk fat and nonfat milk solids when bulky flavors are added to ice milk and revokes revised standards for use of certain safe and suitable milk-derived ingredients and establishment of minimum milk protein requirements. These actions are taken in response to objections to the revised standards for frozen desserts.

EFFECTIVE DATES: Provisions confirmed—July 1, 1979; provisions revoked February 3, 1978.

FOR FURTHER INFORMATION CONTACT:

Eugene T. McGarrahan, Bureau of Foods (HFF-415), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration issued in the FEDERAL REGISTER of April 12, 1977 (42 FR 19127) a final regulation amending the identity standards for frozen desserts, primarily to: (1) Provide for full ingredient declaration of all the frozen desserts; (2) provide for the use of safe and suitable ingredients; and (3) provide for replacing the long-standing use of a nonfat milk solids minimum with a milk protein minimum. The regulation revised and reissued former 21 CFR 135.10, 135.20, 135.40, 135.65, 135.70, and 135.90 as 21 CFR 135.3, 135.110, 135.120, 135.140, and 135.160. Written objections and requests for a hearing were received. As a result of these objections, the Commissioner issued in the FEDERAL REGISTER of July 8, 1977 (42 FR 35152) a document confirming the effective date for the standard of identity for water ices and certain portions of the standards of identity for ice cream, frozen custard, ice milk, and sherbet. He stayed other portions of the ice cream, frozen custard, ice milk, and

sherbet standards pending the receipt and review of information he considered essential to make a final decision on the merits of granting requests for a hearing. He also provided an opportunity for all interested parties to submit more definitive data and information on the issues to which certain objections had been raised. With these data and information available, he stated that he would determine whether to grant or deny the requested hearing.

Pursuant to section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)), the Commissioner has considered the objections and requests for a hearing, the supplemental information and data received in response to his July 8, 1977 regulation and other information that has become available. All the information and data considered are on file with the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. The Commissioner's conclusions follow:

Objections and Request for a Hearing

1. The effectiveness of the provision in the revised standard for reduction in milk solids when bulky flavors are added to ice milk (21 CFR 135.120(a)(2), redesignated 135.120(a)(4) below) is confirmed.

The basis for the objection to this provision was that the standard before revision did not provide for a decrease in the milk solids content of ice milk when various amounts and kinds of bulky flavors are used to characterize ice milk. One comment urged that no allowance be made for bulky flavors in ice milk in order to prevent ice milk from being fraudulently sold as ice cream. No data or information to support this objection were submitted in response to the final regulation or to the Commissioner's July 8, 1977 document.

The Commissioner agrees that the former standard did not provide for the reduction objected to, but no supporting information has been forwarded to support the maintenance of a policy difference between ice milk and ice cream as it concerns bulky flavors. Ice cream manufacturing already makes allowance for bulky flavors, and the submissions provided no bases to support the assertion that the failure to make a similar allowance for bulky flavors in ice milk would help prevent fraud. Furthermore, the sale of ice milk as ice cream or some other different food would violate the act and would be subject to enforcement action. Therefore, the Commissioner concludes that this objection has not presented an issue of fact supported by data and information that warrants a hearing.

2. The provisions in the revised standards for the use of safe and suitable milk-derived ingredients and establishment of minimum milk protein requirements (as cited below) are revoked.

The agency has evaluated the information and data received in response to the July 8, 1977 request for information and has conducted its own studies, which have indicated that the revised standard could result in a reduction in nutrient levels in some frozen desserts. When it issued these standards, FDA did not expect that there would be measurable nutritional differences between ice cream made under the new standard and that made under the present one. But the agency's studies determined that under the new standard some ice cream formulations could have lesser amounts of some nutrients than under the current standard. For this reason, the Commissioner is revoking § 135.110(a)(1) (21 CFR 135.110(a)(1)) to the extent that it permits the use of safe and suitable milk-derived ingredients not specifically listed as permitted in former § 135.30 (c) and (e) (21 CFR 135.30 (c) and (e)). Therefore, former § 135.30 (c) and (e) are incorporated into § 135.110 as new paragraphs (b) and (c). Further, he is revoking § 135.110(a) (2) and (3) to the extent that they establish minimum milk protein requirements, and he is revoking § 135.110(b) (2) and (3), which specify the method of analysis for milk protein and PER. Therefore, from the former § 135.30 the nonfat milk solids requirements of paragraph (a), the whey limitation requirements of paragraph (c) and the caseinate limitation requirement of paragraph (e) are incorporated into § 135.110(a) (2) and (3), (b), and (c), respectively.

The Commissioner is revoking § 135.120(a)(2) (21 CFR 135.120(a)(2)) to the extent that it establishes minimum milk protein requirements. Therefore, the specific requirements of former § 135.40(b) with respect to total milk solids requirements and § 135.40(c) with respect to the caseinate limitation requirements are incorporated into § 135.120(a) (2) and (3), respectively.

The Commissioner also is revoking § 135.140(a)(1) (21 CFR 135.140(a)(1)) to the extent that it permits the use of safe and suitable milk-derived ingredients not specifically listed as permitted in former §§ 135.20 (c) and (e)(7) and 135.65 (c) and (e)(7). Therefore, former §§ 135.20 (c) and (e)(7) and 135.65 (c) and (e)(7) are incorporated into § 135.140 as new paragraphs (b) and (c). Further, he is revoking § 135.140(a)(2) with respect to the provisions for "nonfat milk-derived solids" and "milk-derived solids." Therefore, the requirements of former § 135.20(a) and § 135.65(a) with respect to "nonfat milk solids" are incorporated into § 135.140(a)(2).

Other Matters

It is important to emphasize that the section requiring ingredient labeling is not being revoked and, as confirmed in the Commissioner's July 8, 1977 document, all products initially introduced into interstate commerce on or after July 1, 1979, shall fully comply.

The regulation will permit the use of safe and suitable ingredients, but only if the present requirements with respect to milkfat, nonfat milk solids, and source of dairy ingredients are satisfied, as sought in the objections. The Commissioner advises that vegetable proteins and other nondairy proteins would not be considered suitable ingredients and could not be used in ice cream because in ice cream the protein ingredients come from dairy sources.

The agency intends to examine further the larger issues raised by the ice cream standard debate, such as the concept that manufacturers can use "sale and suitable" ingredients instead of a strict recipe approach. The agency plans to hold hearings before the Commissioner as provided for in 21 CFR Part 15 later this year to gather public comment on this and related food-labeling issues. The information will help FDA decide on a new course of action, if needed, for the frozen dessert standard, particularly on the need to propose minimum nutrient requirements to assure that the use of "safe and suitable" ingredients will not reduce the nutrient levels of ice cream and related products. Any future changes in the frozen dessert standard will be made through a new rulemaking proceeding, after public notice, comments, and opportunity to file objections and request a hearing.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner (21 CFR 5.1), notice is given that no objections raising substantial issues of fact requiring a hearing under section 701(e) of the act were received regarding § 135.120(a)(2) (21 CFR 135.120(a)(2)). Accordingly, the requests for a hearing on the objections regarding a reduction of milk solids when bulky flavors are added are denied. Further, certain provisions of Part 135 are revoked or amended as discussed in this preamble and reflected in the amendments below, thereby making a formal evidentiary public hearing, as provided for in 21 CFR Part 12, on these provisions unnecessary.

Part 135 is amended:

1. By revising § 135.110 to read as follows:

§ 135.110 Ice cream and frozen custard.

(a) *Description.* (1) Ice cream is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section, and may contain one or more of the optional caseinates specified in paragraph (c) of this section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are natural components of flavoring ingredients used or are added in incidental amounts to accomplish specific functions. Ice cream is sweetened with nutritive carbohydrate sweeteners and may or may not be characterized by the addition of flavoring ingredients.

(2) Ice cream contains not less than 1.6 pounds of total solids to the gallon, and weighs not less than 4.5 pounds to the gallon. Ice cream contains not less than 10 percent milkfat, nor less than 10 percent nonfat milk solids, except that when it contains milkfat at 1 percent increments above the 10 percent minimum, it may contain the following milkfat-to-nonfat milk solids levels:

Percent milkfat	*Minimum percent nonfat milk solids*
10	10
11	9
12	8
13	7
14	6

Except that when one or more bulky flavors are used, the weights of milkfat and total milk solids are not less than 10 percent and 20 percent, respectively, of the remainder obtained by subtracting the weight of the bulky flavors from the weight of the finished food; but in no case is the weight of milkfat or total milk solids less than 8 percent and 16 percent, respectively, of the weight of the finished food. Except in the case of frozen custard, ice cream contains less than 1.4 percent egg yolk solids by weight of the food, exclusive of the weight of any bulky flavoring ingredients used. Frozen custard shall contain 1.4 percent egg yolk solids by weight of the finished food: *Provided, however,* That when bulky flavors are added the egg yolk solids content of frozen custard may be reduced in proportion to the amount by weight of the bulky flavors added, but in no case is the content of egg yolk solids in the finished food less than 1.12 percent. A product containing egg yolk solids in excess of 1.4 percent, the maximum set forth in this paragraph for ice cream, may be marketed if labeled as specified by paragraph (e)(1) of this section.

(3) When calculating the minimum amount of milkfat and nonfat milk solids required in the finished food, the solids of chocolate or cocoa used shall be considered a bulky flavoring ingredient. In order to make allowance for additional sweetening ingredients needed when certain bulky ingredients are used, the weight of chocolate or cocoa solids used may be multiplied by 2.5; the weight of fruit or nuts used may be multiplied by 1.4; and the weight of partially or wholly dried fruits or fruit juices may be multiplied by appropriate factors to obtain the original weights before drying and this weight may be multiplied by 1.4.

(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are: Cream, dried cream, plastic cream (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, sweetened condensed milk, superheated condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part-skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, skim milk in concentrated or dried form which has been modifed by treating the concentrated skim milk with calcium hydroxide and disodium phosphate, concentrated cheese whey, and dried cheese whey. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow's milk. Any concentrated cheese whey and dried cheese whey used contribute not more than 25 percent by weight of the total nonfat milk solids content of the finished food. Dried cheese whey is uniformly light in color, free from brown and black scorched particles, and has an alkalinity of ash, not more than 225 milliliters 0.1*N* HCl per 100 grams, a bacterial count of not more than 50,000 per gram, and, as adjusted with water to a total solids content of 6.5 percent, a titratable acidity of not more than 0.16 percent, calculated as lactic acid. Concentrated cheese whey has an alkalinity of ash, not more than 115 milliliters 0.1*N* HCl per 100 grams, a bacterial count of not more than 50,000 per gram, and, as adjusted with water to a total solids content of 6.5 percent, a titratable acidity of not more than 0.18 percent, calculated as lactic acid. The modified skim milk, when adjusted with water to a total solids content of 9 percent is substantially free of lactic acid as determined by titration with 0.1*N* NaOH, and it has a pH value in the range of 8.0 to 8.3.

(c) *Optional caseinates.* The optional caseinates referred to in paragraph (a) of this section that may be added to ice cream mix containing not less than 20 percent total milk solids are: Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinate may be added in liquid or dry form, but must be free of excess alkali.

(d) *Methods of analysis.* Fat content shall be determined by the following methods contained in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th ed., 1975.[1]

(1) Fat content shall be determined by the method: "Fat; Roese-Gottlieb Method—Official Final Action," section 16.228.

(2) [Reserved]

(e) *Nomenclature.* (1) The name of the food is "ice cream"; except that when the egg yolk solids content of the food is in excess of that specified for ice cream by paragraph (a) of this section, the name of the food is "frozen custard" or "french ice cream" or "french custard ice cream".

(2) (i) If the food contains no artificial flavor, the name on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the words "ice cream".

(ii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the natural flavor predominates, the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor, in letters not less than one-half the height of the letters used in the words "ice cream", followed by the word "flavored", in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "Vanilla flavored", or "Peach flavored", or "Vanilla flavored and Strawberry flavored".

(iii) If the food contains both a natural characterizing flavor and an artificial flavor simulating it, and if the artificial flavor predominates, or if artificial flavor is used alone the name on the principal display panel or panels of the label shall be accompanied by the common name of the characterizing flavor in letters not less than one-half the height of the letters used in the words "ice cream", preceded by "artificial" or "artificially flavored", in letters not less than one-half the

[1] Copies may be obtained from: Association of Official Analytical Chemists, Post Office Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

height of the letters in the name of the characterizing flavor, e.g., "artificial Vanilla", or "artifically flavored Strawberry" or "artificially flavored Vanilla and artificially flavored Strawberry".

(3)(i) If the food is subject to the requirements of paragraph (e)(2)(ii) of this section or if it contains any artificial flavor not simulating the characterizing flavor, the label shall also bear the words "artificial flavor added" or "artificial ——— flavor added", the blank being filled with the common name of the flavor simulated by the artificial flavor in letters of the same size and prominence as the words that precede and follow it.

(ii) Wherever the name of the characterizing flavor appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words prescribed by this paragraph shall immediately and conspicuously precede or follow such name, in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over: *Provided, however,* That where the characterizing flavor and a trademark or brand are presented together, other written, printed, or graphic matter that is a part of or is associated with the trademark or brand, may intervene if the required words are in such relationship with the trademark or brand as to be clearly related to the characterizing flavor: *And provided further,* That if the finished product contains more than one flavor of ice cream subject to the requirements of this paragraph, the statements required by this paragraph need appear only once in each statement of characterizing flavors present in such ice cream, e.g., "Vanilla flavored, Chocolate, and Strawberry flavored, artificial flavors added".

(4) If the food contains both a natural characterizing flavor and an artificial flavor simulating the characterizing flavor, any reference to the natural characterizing flavor shall, except as otherwise authorized by this paragraph, be accompanied by a reference to the artificial flavor, displayed with substantially equal prominence, e.g., "strawberry and artificial strawberry flavor".

(5) An artificial flavor simulating the characterizing flavor shall be deemed to predominate:

(i) In the case of vanilla beans or vanilla extract used in combination with vanillin if the amount of vanillin used is greater than 1 ounce per unit of vanilla constituent, as that term is defined in § 169.3(c) of this chapter.

(ii) In the case of fruit or fruit juice used in combination with artificial fruit flavor, if the quantity of the fruit or fruit juice used is such that, in relation to the weight of the finished ice cream, the weight of the fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content) is less than 2 percent in the case of citrus ice cream, 6 percent in the case of berry or cherry ice cream, and 10 percent in the case of ice cream prepared with other fruits.

(iii) In the case of nut meats used in combination with artificial nut flavor, if the quantity of nut meats used is such that, in relation to the finished ice cream the weight of the nut meats is less than 2 percent.

(iv) In the case of two or more fruits or fruit juices, or nut meats, or both, used in combination with artificial flavors simulating the natural flavors and dispersed throughout the food, if the quantity of any fruit or fruit juice or nut meat is less than one-half the applicable percentage specified in paragraph (e)(5) (ii) or (iii) of this section. For example, if a combination ice cream contains less than 5 percent of bananas and less than 1 percent of almonds it would be "artificially flavored banana-almond ice cream". However, if it contains more than 5 percent of bananas and more than 1 percent of almonds it would be "banana-almond flavored ice cream".

(6) If two or more flavors of ice cream are distinctively combined in one package, e.g., "Neapolitan" ice cream, the applicable provisions of this paragraph shall govern each flavor of ice cream comprising the combination.

(f) *Label declaration.* Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter, except that sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of all the terms "milkfat and nonfat milk" when one or any combination of two or more of the ingredients listed in § 101.4(b) (3), (4), (8), and (9) of this chapter are used or alternatively as permitted in § 101.4 of this chapter. Pursuant to section 402(k) of the Federal Food, Drug, and Cosmetic Act artificial color need not be declared in ice cream. Voluntary declaration of such color in ice cream is recommended.

2. By revising § 135.120 to read as follows:

§ 135.120 Ice milk.

(a) *Description.* Ice milk is the food prepared from the same ingredients and in the same manner prescribed in § 135.110 for ice cream and complies with all the provisions of § 135.110 (including the requirements for label statement of optional ingredients), except that:

(1) Its content of milkfat is more than 2 percent but not more than 7 percent.

(2) Its content of total milk solids is not less than 11 percent.

(3) Caseinates may be added when the content of total milk solids is not less than 11 percent.

(4) The provision for reduction in milkfat and nonfat milk solids content from the addition of bulky flavors in § 135.110(a) applies, except that in no case will the milkfat content be less than 2 percent, nor the nonfat milk solids content be less than 7 percent. When the milkfat content increases in increments of 1 percent above the 2 percent minimum, it may contain the following milkfat-to-nonfat milk solids levels:

Percent milkfat	*Minimum percent nonfat milk solids*
2	9
3	8
4	7
5	6
6	5
7	4

(5) The quantity of food solids per gallon is not less than 1.3 pounds.

(6) When any artificial coloring is used in ice milk, directly or as a component of any other ingredient, the label shall bear the statement "artificially colored", "artificial coloring added", "with added artificial color", or "———, an artificial color added", the blank being filled in with the common or usual name of the artificial color; or in lieu thereof, in case the artificial color is a component of another ingredient, "——— artificially colored".

(7) If both artificial color and artificial flavoring are used, the label statements may be combined.

(b) *Nomenclature.* The name of the food is "ice milk".

3. By revising § 135.140 to read as follows:

§ 135.140 Sherbet.

(a) *Description.* (1) Sherbet is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section, and may contain one or more of the optional caseinates specified in paragraph (c) of this section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are added in small amounts to accomplish specific functions or are natural components of flavoring ingredients used. Sherbet is sweetened with nutritive carbohydrate sweeteners and is char-

acterized by the addition of one or more of the characterizing fruit ingredients specified in paragraph (b) of this section or one or more of the nonfruit-characterizing ingredients specified in paragraph (c) of this section.

(2) Sherbet weighs not less than 6 pounds to the gallon. The milkfat content is not less than 1 percent nor more than 2 percent, the nonfat milk-derived solids content not less than 1 percent, and the total milk or milk-derived solids content is not less than 2 percent nor more than 5 percent by weight of the finished food. Sherbet that is characterized by a fruit ingredient shall have a titratable acidity, calculated as lactic acid, of not less than 0.35 percent.

(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are: Cream, dried cream, plastic cream (sometimes known as concentrated milk fat), butter, butter oil, milk, concentrated milk, evaporated milk, superheated condensed milk, sweetened condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, condensed skim milk, superheated condensed skim milk, sweetened condensed skim milk, sweetened condensed part-skim milk, nonfat dry milk, sweet cream buttermilk, condensed sweet cream buttermilk, dried sweet cream buttermilk, skim milk that has been concentrated and from which part of the lactose has been removed by crystallization, concentrated cheese whey, and dried cheese whey. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow's milk. Dried cheese whey is uniformly light in color, free from brown and black scorched particles, and has an alkalinity of ash, not more than 225 milliliters 0.1*N* HCl per 100 grams, a bacterial count of not more than 50,000 per gram, and, as adjusted with water to a total solids content of 6.5 percent, a titratable acidity of not more than 0.16 percent calculated as lactic acid. Concentrated cheese whey has an alkalinity of ash, not more than 115 milliliters 0.1*N* HCl per 100 grams, a bacterial count of not more than 50,000 per gram, and, as adjusted with water to a total solids content of 6.5 percent, a titratable acidity of not more than 0.18 percent, calculated as lactic acid.

(c) *Optional caseinates.* The optional caseinates referred to in paragraph (a) of this section which may be added to sherbet mix are: Casein prepared by precipitation with gums, ammonium caseinate, calcium caseinate, potassium caseinate, and sodium caseinate. Caseinates may be added in liquid or dry form, but must be free of excess alkali, Such caseinates are not considered to be milk solids.

(d) *Optional fruit-characterizing ingredients.* The optional fruit-characterizing ingredients referred to in paragraph (a) of this section are any mature fruit or the juice of any mature fruit. The fruit or fruit juice used may be fresh, frozen, canned, concentrated, or partially or wholly dried. The fruit may be thickened with pectin or other optional ingredients. The fruit is prepared by the removal of pits, seeds, skins, and cores, where such removal is usual in preparing that kind of fruit for consumption as fresh fruit. The fruit may be screened, crushed, or otherwise comminuted. It may be acidulated. In the case of concentrated fruit or fruit juices, from which part of the water is removed, substances contributing flavor volatilized during water removal may be condensed and reincorporated in the concentrated fruit or fruit juice. In the case of citrus fruits, the whole fruit, including the peel but excluding the seeds, may be used, and in the case of citrus juice or concentrated citrus juices, cold-pressed citrus oil may be added thereto in an amount not exceeding that which would have been obtained if the whole fruit had been used. The quantity of fruit ingredients used is such that, in relation to the weight of the finished sherbet, the weight of fruit or fruit juice, as the case may be (including water necessary to reconstitute partially or wholly dried fruits or fruit juices to their original moisture content), is not less than 2 percent in the case of citrus sherbets, 6 percent in the case of berry sherbets, and 10 percent in the case of sherbets prepared with other fruits. For the purpose of this section, tomatoes and rhubarb are considered as kinds of fruit.

(e) *Optional nonfruit characterizing ingredients.* The optional nonfruit characterizing ingredients referred to in paragraph (a) of this section include but are not limited to the following:

(1) Ground spice or infusion of coffee or tea.

(2) Chocolate or cocoa, including sirup.

(3) Confectionery.

(4) Distilled alcoholic beverage, including liqueurs or wine, in an amount not to exceed that required for flavoring the sherbet.

(5) Any natural or artificial food flavoring (except any having a characteristic fruit or fruit-like flavor).

(f) *Nomenclature.* (1) The name of each sherbet is as follows:

(i) The name of each fruit sherbet is "——— sherbet", the blank being filled in with the common name of the fruit or fruits from which the fruit ingredients used are obtained. When the names of two or more fruits are included, such names shall be arranged in order of predominance, if any, by weight of the respective fruit ingredients used.

(ii) The name of each nonfruit sherbet is "——— sherbet", the blank being filled in with the common or usual name or names of the characterizing flavor or flavors; for example, "peppermint", except that if the characterizing flavor used is vanilla, the name of the food is "——— sherbet", the blank being filled in as specified by § 135.110(e) (2) and (5)(i).

(2) When the optional ingredients, artificial flavoring, or artificial coloring are used in sherbet, they shall be named on the label as follows:

(i) If the flavoring ingredient or ingredients consists exclusively of artificial flavoring, the label designation shall be "artificially flavored".

(ii) If the flavoring ingredients are a combination of natural and artificial flavors, the label designation shall be "artificial and natural flavoring added".

(iii) The label shall designate artificial coloring by the statement "artificially colored", "artificial coloring added", "with added artificial coloring", or "———, an artificial color added", the blank being filled in with the name of the artificial coloring used.

(g) *Characterizing flavor(s).* Wherever there appears on the label any representation as to the characterizing flavor or flavors of the food and such flavor or flavors consist in whole or in part of artificial flavoring, the statement required by paragraph (f)(2) (i) and (ii) of this section, as appropriate, shall immediately and conspicuously precede or follow such representation, without intervening written, printed, or graphic matter (except that the word "sherbet" may intervene) in a size reasonably related to the prominence of the name of the characterizing flavor and in any event the size of the type is not less than 6-point on packages containing less than 1 pint, not less than 8-point on packages containing at least 1 pint but less than one-half gallon, not less than 10-point on packages containing at least one-half gallon but less than 1 gallon, and not less than 12-point on packages containing 1 gallon or over.

(h) *Display of statements required by paragraph (f)(2).* Except as specified in paragraph (g) of this section, the statements required by paragraph (f)(2) of this section shall be set forth on the principal display panel or panels of the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(i) *Label declaration.* Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

Effective date: Compliance with the confirmed provision of this regulation, including any required labeling changes, may have begun on June 13, 1977, and all products initially introduced into interstate commerce on or after July 1, 1979, shall fully comply. As to the provisions hereby revoked, the effective date is February 3, 1978.

(Secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)).)

Dated: January 30, 1978.

DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc. 78-2967 Filed 2-2-78; 8:45 am]

[4110-03]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Diethylcarbamazine Citrate Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval for a new animal drug application (NADA) providing for use of an antintic tablet as an aid in treatment of ascarids in dogs and cats and prevention of heartworm disease in dogs. The application was filed by Philips Roxane, Inc.

EFFECTIVE DATE: February 3, 1978.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Philips Roxane, Inc., St. Joseph, Mo. 64502, filed an NADA (108-487V) providing for use of diethylcarbamazine citrate tablets as an aid in treatment of ascarids (*T. canis* and *T. leonina*) in dogs and cats and prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

In accordance with the freedom of information regulations and § 514.11 (e)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of the safety and effectiveness data and information submitted to support the approval of this application is released publicly. The summery is available for public examination at the office of the Hearing Clerk (HFC-20), Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between 9 a.m. and 4 p.m., Monday through Friday, except on Federal holidays.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i) 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 520 is amended in § 520.622a by revising paragraph (a) to read as follows:

§ 520.622a Diethylcarbamazine citrate tablets.

(a) (1) *Specifications.* Each tablet contains 50, 200, or 400 milligrams of diethylcarbamizine citrate.

(2) *Sponsors.* See Nos. 000010 and 010042 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* (*a*) 25 to 50 milligrams per pound of body weight as an aid in treatment of ascarid infections.

(*b*) 3 milligrams per pound of body weight daily for prevention of heartworm disease.

(ii) *Indications for use.* As an aid in treatment of ascarid (*Toxocara canis* and *Toxascaris leonina*) infections in dogs and cats; for prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(iii) *Limitations.* Tablets are administered orally or pulverized and given in the feed or water. For treatment of ascarids, a repeat dose should be given in 10 to 20 days to remove immature worms that may enter the intestine from the lungs after the first dose. Dogs with established heartworm infections should not receive the drug until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm infected dogs may cause adverse reactions due to pulmonary occlusion. Overdosage may cause emesis. For prevention of heartworm disease in heartworm endemic areas, administration of the drug should start at the beginning of mosquito activitiy and be continued daily throughout the mosquito season and for approximately a month thereafter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

Effective date: February 3, 1978.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: January 24, 1978.

FRED J. KINGMA,
Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 78-2826 Filed 2-2-78; 8:45 am]

[4110-03]

PART 540—PENICILLIN ANTIBIOTIC DRUGS FOR ANIMAL USE

Amoxicillin Trihydrate Oral Suspension

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a new animal drug application (NADA) filed by Beecham Laboratories providing for orse of an amoxicillin suspension for treatment of porcine colibacillosis in baby pigs.

EFFECTIVE DATE: February 3, 1978.

FOR FURTHER INFORMATION CONTACT:

Charles E. Haines, Bureau of Veterinary Medicine (HFV-138), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3410.

SUPPLEMENTARY INFORMATION: Beecham Laboratories, Division of Beecham, Inc., Bristol, Tenn. 37620, filed an NADA (55-080V) providing for use of amoxicillin trihydrate oral suspension in treating porcine colibacillosis in pigs under 4 weeks of age.

In accordance with the freedom of information regulations and § 514.11(e)(2)(ii) of the animal drug regulations, a summary of safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFC-20), Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, Monday through Friday, from 9 a.m. to 4 p.m., except on Federal holidays.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 540 is amended by adding new § 540.103c to read as follows:

§ 540.103c Amoxicillin trihydrate oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Amoxicillin trihydrate oral suspension is composed of amoxicillin trihydrate with a suitable and harmless preservative and gelling agent suspended in soybean oil base. The drug is packaged in a multiple-dose container incorporating a suitable dosing pump. Each 0.8-milliter dose contains amoxicillin trihydrate equivalent to 40 milligrams of amoxicillin. Its potency is satisfactory if it is not less than 90 percent and not more