§ 184.1257 Clove and its derivatives.

(a) Cloves are the dried unopened flower buds and calyx tubes, harvested before the flowers have opened, of the clove tree *Eugenia caryophyllata* Thunberg, native to tropical Asia. Their derivatives include essential oils (cloves, CAS Reg. No. 8000-34-8; buds; leaves, CAS Reg. No. 8015-97-2; stems, CAS Reg. No. 8015-98-3; and eugenol, CAS Reg. No. 97-53-0), oleoresins, and natural extractives obtained from clove buds, leaves, and stems.

(b) Clove bud oil, clove leaf oil, clove stem oil, and eugenol meet the specifications of the Food Chemicals Codex (FCC), 2d Ed. (1972),[1] which is incorporated by reference. As determined by analytical methods in FCC, clove oleoresin or other natural extractives (other than clove oils) meet FCC specifications for clove (clove bud) oil and the following modifications:

(1) The assay for phenols, as eugenol, by the FCC test (p. 898) or the volatile oils content by the FCC test (p. 901) should conform to the representation of the vendor;

(2) Optical rotation of the volatile oil between −2° and 0°;

(3) Refractive index of the volatile oil between 1.527 and 1.538 at 20° C;

(4) Specific gravity of the volatile oil between 1.036 and 1.060; and

(5) Residual solvent free, except those solvents that are GRAS or within tolerance levels as specified in Part 173, Subpart C, of this chapter.

(c) Clove and its derivatives are used as flavoring agents and adjuvants as defined in § 170.3(o)(12) of this chapter.

(d) The ingredients are used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1).

(e) Prior sanctions for these ingredients different from the uses established in this section do not exist or have been waived.

Effective date. This regulation is effective February 20, 1979.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a)))

NOTE.—Incorporation by reference was approved by the Director of the Office of the Federal Register on July 10, 1973 and is on file in the FEDERAL REGISTER library.

Dated: January 15, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-1904 Filed 1-18-79; 8:45 am]

[1] Copies may be obtained from: National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20037.

[4110-03-M]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 77N-0119]

PART 131—MILK AND CREAM

Nonfat Dry Milk, Lowfat Dry Milk, Dry Whole Milk, and Dry Cream; Standards of Identity; Confirmation of Effective Date and a Further Amendment

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document confirms the effective date of the final regulation of May 9, 1978 that amended the standards of identity for nonfat dry milk and nonfat dry milk fortified with vitamins A and D and established standards of identity for lowfat dry milk, dry whole milk, and dry cream based on consideration of the international standards developed by the Codex Alimentarius Commission for these foods. This document also amends the description for dry cream to make it consistent with the descriptions for dry whole milk and lowfat dry milk.

DATES: Voluntary compliance may have begun July 10, 1978. Mandatory compliance for all products initially introduced into interstate commerce begins July 1, 1979. Objections to the amendment by February 20, 1979.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs issued a final regulation in the FEDERAL REGISTER of May 9, 1978 (43 FR 19834) that established standards of identity for low fat dry milk, dry whole milk, and dry cream (21 CFR 131.123, 131.147, and 131.149, respectively) and amended the standards of identity for nonfat dry milk and nonfat dry milk fortified with vitamins A and D (21 CFR 131.125 and 131.127, respectively). The new standards of identity were based on the recommended international standards for whole milk powder, partly skimmed milk powder, and skimmed milk powder (Codex Standard No. A-5 (1971)) and the recommended international standards for cream powder, half cream powder, and high-fat milk powder (Codex Standard No. A-10 1971)) which were submitted to the United States for consideration of acceptance by the Joint Food and Agriculture Organization/World Health Organization's Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products, and auxiliary body of the Codex Alimentarius Commission. The new standards of identity for lowfat dry milk, dry whole milk, and dry cream establish (1) requirements for mandatory ingredients, (2) provisions for optional ingredients such as stabilizers, emulsifiers, anticaking agents, antioxidants, and characterizing flavoring ingredients, with or without coloring, and (3) requirements for label declaration of optional ingredients. In addition, the standards of identity for nonfat dry milk and nonfat dry milk fortified with vitamins A and D were amended to provide for the use of nutritive carbohydrate sweetners in the optional characterizing flavoring ingredients.

The final regulation provided that any person who would be adversely affected could at any time, on or before June 8, 1978, file written objections to the final regulation and request a hearing on the specific provisions to which there were objections.

OBJECTIONS AND REQUESTS FOR A HEARING

Two objections and requests for a hearing and one letter suggesting a minor change were received in response to the final regulation. The Commissioner has considered these responses and his conclusions are as follows:

1. *Description of dry cream.* The American Dry Milk Institute (ADMI) suggested that the standard of identity for dry cream provide for the manufacture of dry cream by dry blending dry cream with other dry milk products even though this method is not currently common practice in the United States. The ADMI is of the opinion that this would (1) make the description of dry cream in § 131.149(a) uniform with the descriptions of lowfat dry milk in § 131.123(a) and dry whole milk in § 131.147(a); and (2) allow flexibility without restricting future manufacturing processes for dry cream.

The Commissioner agrees with ADMI's suggestions and is revising the standard of identity for dry cream accordingly.

2. *Lactose-reduced dry milk products.* Two firms marketing the enzyme lactase objected to the establishment of the standards of identity for lowfat dry milk, dry whole milk, and dry cream, and the amendment of the standard of identity for nonfat dry milk. They maintained that the final regulations, as published, will adversely affect them and will not be in the

best interest of consumers. They stated that the standards of identity establish the level of lactose contained in the foods, thereby eliminating lactose-reduced dry milk products as foods that can be made and sold under the standard nomenclature. The firms said that alternate nomenclature such as "lactose reduced skim milk solids" would have to be substituted for the preferred "lactose reduced nonfat dry milk." Further, they stated that this exclusion from standard product nomenclature obscures the product's identity and causes unnecessary confusion for the the consumer. Further, they said that the conversion of lactose to the more readily digestible galactose and glucose, resulting from the treatment of milk with lactase, is beneficial to that segment of the population, estimated at about 30 million in the United States, that cannot readily tolerate lactose in its naturally occuring form. The firms suggested that consideration be given to other foods that may be produced with lactose in the hydrolyzed form for which standards of identity not exist or will be developed in the future.

The Commissioner recognizes the benefits to be derived from lactose reduced milk products by lactose-intolerant individuals but does not believe that there is a need to delay issuing the standards of identity for dry milk products in order to establish appropriate names for lactose-reduced milk products. Lactose-reduced milk products differ in composition from dry milk products. As the objectors recognize, the lactose-reduced foods cannot bear the same name as dry milk products but must instead be named to indicate their distinctive feature. However, they do not have to be labeled with obscure names as suggested by the objectors. Furthermore, as the Commissioner has previously advised in the FEDERAL REGISTER of August 2, 1973 (38 FR 20703), the existence of a standard of identity for a particular food does not necessarily preclude the use of the standardized name in connection with the name of a nonstandardized food, and "in some cases it may be necessary to include a standardized name in the name of a substitute food in order to provide the consumer with accurate, descriptive, and fully informative labeling." In other words, the standards of identity to which objections are made do not by themselves, affect the objecting parties' ability to market accurately labeled lactose-reduced milk products using the standardized nomeclature, to the extent appropriate, as part of the name of the new foods.

Accordingly, the Commissioner is denying a hearing on the points made in the objections because they do not raise factual issues concerning the validity of the standards of identity in question. Rather, the objections seek to avoid an effect that the standards do not have by seeking to establish new names for distinct foods that are not subject to the standards; the promulgation of these standards for dry milk products will not preclude the development of appropriate names for the new product. Under 21 CFR 12.24(b)(4), a hearing will not be granted when a food standard does not have the effect of excluding or otherwise affecting the products. The lactose-reduced foods may be sold as nonstandardized foods named in accordance with the general principles in 21 CFR 102.5. Alternatively, the objectors may file a petition to establish a new standard of identity for these products. Since the lactose-reduced foods are special dietary foods, the foods should also comply with the applicable labeling requirements in Part 105.

A GRAS affirmation petition for lactase enzyme derived from *Kluyveromyces* (*Saccharomyces*) *lactis*, submitted by one of the objectors, is being considered by the agency. No decision has been made regarding its safety. In view of the undetermined status of this source of lactase enzyme and the option for production of lactose-reduced milk products as special dietary foods, the Commissioner concludes that a hearing on the above objections is not warranted.

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 the objections filed to the final regulation establishing standards of identity for lowfat dry milk, dry whole milk, and dry cream under §§ 131.123, 131.147, and 131.149 and amending the standards of identity for nonfat dry milk and nonfat dry milk fortified with vitamins A and D under §§ 131.125 and 131.127 are not accepted as valid, except that, in accordance with the foregoing: *It is ordered*, That § 131.149 as promulgated in the FEDERAL REGISTER of May 9, 1978, be amended by revising paragraph (a) to read as follows:

§ 131.149 Dry cream.

(a) *Description.* Dry cream is the product obtained by removal of water only from pasteurized milk or cream or a mixture thereof, which may have been homogenized. Alternatively, dry cream may be obtained by blending dry milks as defined in §§ 131.123(a), 131.125(a), and 131.147(a) with dry cream as appropriate: *Provided*, That the resulting product is equivalent in composition to that obtained by the method described in the first sentence of this paragraph. It contains not less than 40 percent but less than 75 percent by weight of milkfat on an as is basis. It contains not more than 5 percent by weight of moisture on a milk solids not fat basis.

* * * * *

Any person who will be adversely affected by the foregoing amendment to the final regulation may at any time on or before February 20, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description an analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: Except as to the amendment that may be stayed by the filing of proper objections, compliance with this amendment to the final regulation may begin Feburary 20, 1979. Notice of the filing of objections or lack thereof will be published in the FEDERAL REGISTER. Compliance with all other provisions of the final regulation may have begun on July 10, 1978, and all products initially introduced into interstate commerce on or after July 1, 1979, shall fully comply.

Dated: January 11, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-1560 Filed 1-18-79; 8:45 am]

[4110-03-M]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 510—NEW ANIMAL DRUGS

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Selenium Disulfide Suspension

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the regulations to reflect approval of a new animal drug application (NADA) filed by Farnam Companies, Inc., providing for use of a selenium disulfide suspension on dogs as a shampoo and agent for removing skin debris, and to indicate the sponsor's current corporate address.

EFFECTIVE DATE: January 19, 1979.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: Farnam Companies, Inc., 2230 E. Magnolia St., Phoenix, AZ 85036, filed an NADA (115-579V) providing for use of a selenium disulfide suspension on dogs as a cleansing shampoo and as an agent for removing skin debris associated with dry eczema and nonspecific dermatoses.

This application concerns a product similar to one reviewed by the National Academy of Sciences/National Research Council (NAS/NRC), approval of which is reflected in the regulations in § 524.2101 (21 CFR 524.2101). This application is approved on the basis of generic equivalence to the NAS/NRC reviewed product. It conforms to the NAS/NRC panel recommendations published in the FEDERAL REGISTER of September 5, 1970 (35 FR 14168).

In addition, the regulations do not reflect the current address of the firm in the list of approved sponsors in § 510.600(c) (21 CFR 510.600(c)). The address is revised appropriately.

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 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 (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

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) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Parts 510 and 524 are amended as follows:

1. In Part 510, § 510.600 is amended by revising the entries for Farnam Companies, Inc., in paragraph (c) (1) and (2) to read as follows:

§ 510.600 Names, addresses, and code number of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug listing No.
* * * * *	
Farnam Companies, Inc., 2230 E. Magnolia St., Phoenix, AZ 85036;	017135.
* * * * *	

(2) * * *

Drug listing No.	Firm name and address
* * * * *	
017135;	Farnam Companies, Inc., 2230 E. Magnolia St., Phoenix, AZ 85036.
* * * * *	

2. In Part 524, § 524.2101 is amended by revising paragraph (b)(2) to read as follows:

§ 524.2101 Selenium disulfide suspension.

* * * * *

(b) * * *

(2) See Nos. 011536, 015563, and 017135 in § 510.600(c) of this chapter for use as in paragraph (c)(2)(ii) of this section.

* * * * *

Effective date. This regulation is effective January 19, 1979.

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

Dated: January 10, 1979.

LESTER M. CRAWFORD,
Director, Bureau of Veterinary Medicine.

[FR Doc. 79-1903 Filed 1-18-79; 8:45 am]

[4110-03-M]

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

Diethylcarbamazine Citrate Syrup

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) providing for safe and effective use of an anthelmintic syrup for prevention of heartworm disease in dogs and as an aid in treatment of ascarid infections in dogs and cats. The application was filed by Evsco Pharmaceutical Corp.

EFFECTIVE DATE: January 19, 1979.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: Evsco Pharmaceutical Corp., P.O. Box 209, Harding Highway, Buena, NJ 08310, filed an NADA (100-689V) providing for use of diethylcarbamazine citrate syrup for prevention of heartworm disease (*Dirofilaria immitis*) in dogs and as an aid in treatment of ascarid infections in dogs (*Toxocara canis*) and cats (*Toxocara canis* and *Toxascaris leonina*). The regulations are amended to add Evsco as a sponsor and revise the existing text in accordance with the current format.

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 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 (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m to 4 p.m., Monday through Friday.

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