the SFAR flight operations dealing with essential military, medical and rescue, essential public health and welfare, Presidential and Vice Presidential delegations, visiting heads of state, the Olympic Committee and media whose planned activities have been coordinated with and accredited by the Atlanta Committee for the Olympic Games and law enforcement and security officials.

As circumstances may warrant, it may be necessary for the appropriate Regional Administrator to exercise the authority as stated above and provided for in paragraph A.3 of SFAR No. 74. This delegation will enable the Regional Administrator for the Southern Region to administer the provisions of paragraph A.3. of SFAR No. 74.

Delegation

Accordingly, I hereby delegate my authority to administer paragraph A.3. of SFAR No. 74 to the Regional Administrator of the Southern Region.

Issued in Washington, DC on June 3, 1996.

David R. Hinson,

Administrator.

[FR Doc. 96–17588 Filed 7–9–96; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 88G–0388]

Direct Food Substances Affirmed as Generally Recognized as Safe; Cocoa Butter Substitute Derived From High-Oleic Safflower or Sunflower Oil

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that cocoa butter substitute manufactured from high-oleic safflower or sunflower oil is generally recognized as safe (GRAS). This action is in response to a petition filed by Fuji Oil Co., Ltd. (Fuji).

DATES: Effective July 10, 1996.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW.,Washington, DC 20204, 202–418–3097.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in § 170.35 (21 CFR 170.35), Fuji Oil Co., Ltd., 6–1, Hachiman-cho, Minami-ku, Osaka 542, Japan, submitted a petition (GRASP 8G0348) requesting that § 184.1259 (21 CFR 184.1259) be amended to affirm that the use of safflower or sunflower oil in the manufacture of cocoa butter substitute is GRAS.

In the Federal Register of January 26, 1989 (54 FR 3853), FDA published a notice of filing of Fuji's petition and gave interested parties an opportunity to submit comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. FDA received three comments in response to that notice. These comments are discussed below.

In the filing notice, the agency gave notice that the petition had requested that § 184.1259 be amended to permit the use of safflower or sunflower oil in the manufacture of cocoa butter substitute. However, the petition requested, and the agency evaluated, the use of high-oleic safflower or sunflower oil in the manufacture of cocoa butter substitute. Therefore, because the filing notice did not make clear that the proposed starting materials for the manufacture of the petitioner's cocoa butter substitute are high-oleic rather than the typical high-linoleic safflower and sunflower oils, the agency published an amended filing notice in the Federal Register of April 28, 1995 (60 FR 20998), to give interested persons an opportunity to comment with respect to the above-mentioned change. No comments were received in response to the amended filing notice.

II. Standards for GRAS Affirmation

Pursuant to § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances added to food. The basis of such views may be either: (1) Scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, experience based on common use in food (§ 170.30(a)). General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive, and ordinarily is to be based upon generally available data and information concerning the pre-1958 history of use of the substance in food (§ 170.30(c)(1)).

Cocoa butter substitute from high-oleic safflower or sunflower oil was not used in food prior to 1958, and therefore cannot qualify for GRAS status based on a history of common use in food (§ 170.30(c)). Accordingly, FDA has evaluated the ingredient on the basis of scientific procedures (§ 170.30(b)).

In evaluating this petition, the agency reviewed data and information concerning: (1) The chemical composition of the cocoa butter substitute; (2) the process used to manufacture it; (3) the functional equivalence of the cocoa butter substitute to cocoa butter substitute made from palm oil; (4) use of the cocoa butter substitute in food; and (5) information regarding the safety of the cocoa butter substitute.

III. Identity, Specifications, and Manufacturing Process

The common or usual name of the petitioned substance is ''cocoa butter substitute primarily from high-oleic safflower or sunflower oil.'' Its chemical name is 1,3-distearoyl-2-olein (CAS Reg. No. 2846–04–0). The petitioner provided evidence to demonstrate that the specifications for cocoa butter substitute primarily from high-oleic safflower or sunflower oil conform to those for cocoa butter substitute primarily from palm oil, 1-palmitoyl-2-oleoyl-3-stearin, which are set forth in § 184.1259(b)(1) through (b)(9).

Traditional safflower and sunflower oils typically contain high levels of linoleic acid and low levels of oleic acid. However, in the manufacture of its cocoa butter substitute, Fuji uses high-oleic acid-containing safflower or sunflower oil. The high-oleic acid varieties of safflower and sunflower were obtained through common breeding techniques and are the subjects of several published articles (Refs. 1 through 7).

According to Fuji, its cocoa butter substitute is manufactured by reacting ethyl stearate (obtained from food-grade stearic acid) with high-oleic safflower oil or sunflower oil under nitrogen gas in the presence of a catalyst (lipase enzyme preparation adsorbed onto granular celite (diatomaceous earth)) at 37 to 47 °C for 48 hours. After completion of the reaction, the catalyst

is removed by filtration. The remaining free fatty acids and ethyl esters of fatty acids are distilled off at high temperature under vacuum. The reaction product is fractionated with hexane to remove high- and low-melting point fractions and refined by the ordinary refining process for edible fats and oils (deacidification, bleaching, deodorization).

IV. Functional Equivalence to Cocoa Butter Substitute Primarily from Palm Oil

Cocoa butter substitutes have been described as nonhydrogenated vegetable oils that contain a monounsaturated fatty acid at the 2 position and saturated fatty acids at the 1 and 3 positions (Ref. 8).

Cocoa butter substitute derived from palm oil is a mixture of triglycerides containing oleic acid at the 2 position and saturated fatty acids (mostly palmitic and stearic acids) at the 1 and 3 positions. Cocoa butter substitute from high-oleic safflower or sunflower oil is a mixture of triglycerides containing oleic acid at the 2 position and mostly stearic acid at the 1 and 3 positions.

Although the fatty acid composition of cocoa butter substitute from high-oleic safflower or sunflower oil is different from that of cocoa butter substitute derived from palm oil (higher in stearic acid and lower in palmitic acid content), this difference in composition does not affect the function of this cocoa butter substitute in food (Ref. 9). The petitioner provided a published study by Feuge, et al. (Ref. 10), who tested three mixtures (one consisting essentially of oleopalmitostearin, another consisting essentially of oleostearin, and a third consisting mostly of oleopalmitin) for their ability to function as cocoa butter substitutes. The results showed that all three products, when mixed with cocoa butter, had melting properties closely resembling those of cocoa butter and therefore could be satisfactory cocoa butter substitutes. Further, the petitioner stated that although cocoa butter substitute from high-oleic safflower or sunflower oil by itself can be used to make chocolate, it can also be blended with other approved triglycerides to produce a cocoa butter substitute that is similar in chemical composition to natural cocoa butter and to cocoa butter substitute primarily from palm oil.

V. Use in Food

The petitioned use of the ingredient is in the following food categories: confections and frostings as defined in § 170.3(n)(9) (21 CFR 170.3(n)(9)); in coatings of soft candy as defined in § 170.3(n)(38); and in sweet sauces and toppings as defined in § 170.3(n)(43). The petition proposes that use of the ingredient in food be limited to levels consistent with current good manufacturing practice (CGMP).

VI. Safety Information

The petition relies in part on the data developed to establish the safety of cocoa butter substitute derived from palm oil. Section 184.1259 provides for the interesterification of partially saturated 1,2,3-triglycerides (derived from palm oil) with ethyl stearate in the presence of a suitable lipase enzyme preparation. This is also used in the manufacture of the cocoa butter substitute derived from high-oleic safflower or sunflower oil.

Cocoa butter substitute made from high-oleic safflower or sunflower oil consists predominantly of the triglyceride 1,3-distearoyl-2-oleine. The components of this cocoa butter substitute are glycerol and oleic and stearic acids. These components are naturally found as part of glycerides, lipids, lipoproteins, and membranes of both plants and animals. Moreover, they are the same fatty acids and glycerol components as are found in a broad range of edible fats and oils that are GRAS. The synthesis and metabolism of these substances are well understood and are documented in biochemistry textbooks (for example, Ref. 11).

The only difference between cocoa butter substitute derived from high-oleic safflower or sunflower oil, on the one hand, and cocoa butter substitute derived from palm oil, on the other hand, is a difference in fatty acid composition, specifically, the ratio of stearic acid to palmitic acid. The agency finds that this difference does not pose a safety concern. Both of these fatty acids have been safely consumed as common, naturally-occurring compounds in foods (Ref. 12), and the proposed use will not change dietary consumption significantly. Therefore, the agency concludes that cocoa butter substitute prepared from high-oleic safflower or sunflower oil is equivalent to cocoa butter substitute prepared from palm oil with respect to safety, provided it meets the specifications for the similar palm oil-derived product.

Further, the petitioner submitted three published studies to support its contention that cocoa butter substitute made from high-oleic safflower or sunflower oil is safe (Refs. 13 through 15). The studies included an acute oral toxicity study in rats, a subchronic (90-day) oral toxicity study in rats, and a study to assess mutagenicity in bacteria. The bacterial study showed that cocoa butter substitute derived from high-oleic safflower or sunflower oil is not mutagenic; no significant effects from consumption of the cocoa butter substitute were found in the acute and subchronic toxicity studies.

VII. Response to Comments

FDA received three comments in response to the notice announcing the filing of the petition. All of the comments supported the proposed GRAS affirmation of cocoa butter substitute derived from high-oleic safflower or sunflower oil.

Two comments stated that the GRAS affirmation regulation should provide for the use of food-grade stearic acid as an alternative to ethyl stearate as a starting material in manufacturing the petitioned cocoa butter substitute. The comments asserted that it was common industry practice to use both ethyl stearate and stearic acid in interesterification reactions. In addition, the comments pointed out that not only is stearic acid a natural metabolite, but food-grade stearic acid is affirmed as GRAS (21 CFR 184.1090), and FDA permits the use of stearic acid as a raw material to produce various substances approved as food additives, including polysorbate 60, polysorbate 65, sorbitan monostearate, and calcium stearoyl-2-lactylate (21 CFR 172.836, 172.838, 172.842, and 172.844, respectively). Moreover, the comments asserted that stearic acid is a more desirable starting material than ethyl stearate because an end product cocoa butter substitute devoid of residual fatty acid ethyl esters can be produced.

The agency finds that, although the petitioner stated that ethyl stearate would be used as a starting material in the interesterification reaction during the manufacturing of its cocoa butter substitute, it is also common industry practice to use stearic acid in the manufacturing process (Ref. 16). Further, the agency notes that ethyl stearate is itself made from the GRAS substance stearic acid. In essence, direct use of stearic acid in the interesterification reaction bypasses the intermediate step of first converting stearic acid to ethyl stearate. The resulting cocoa butter substitute is the same regardless of whether ethyl stearate or stearic acid is used in the manufacturing process. Therefore, the agency agrees that the direct use of stearic acid as a starting material, without first converting it to ethyl stearate, does not affect the GRAS status of the petitioned cocoa butter substitute. Moreover, the agency concludes that an opportunity for public comment on the

direct use of stearic acid as a starting material is not necessary because the two substances are so closely related. Therefore, in amending § 184.1259, the agency is including stearic acid as an alternative raw material in the manufacture of cocoa butter substitute from high-oleic safflower or sunflower oil.

One of the comments also stated that acetone should be allowed as a solvent in the fractional crystallization of the petitioned cocoa butter substitute during the manufacturing process and suggested a residual acetone specification of not more than 5 parts per million. The comment stated that acetone is a well-recognized solvent in the edible oils industry and cited a number of FDA regulations that permit its use as a solvent. Indeed, acetone is approved as an extractant for annatto extract (21 CFR 73.30(a)(1)(ii)), as a diluent for color additive mixtures made with D&C Red No. 39 (21 CFR 74.1339(a)(2)), as an optional bleaching ingredient with flour (21 CFR 137.105(a)(6)), as a processing solvent in the manufacture of the food additive *N*-acetyl-L-methionine (21 CFR 172.372(a)(4)) and in the extraction of spice (21 CFR 173.210). The agency notes that the safety of the use of acetone as a solvent is well recognized in the food oil industry. However, the agency has no basis to set a specification for residual acetone because it did not evaluate the use of acetone as a solvent in manufacturing cocoa butter substitute. The agency also notes that, as always, any residual solvent that becomes or may reasonably be expected to become a functional component of food must be an approved food additive or GRAS for use in that food.

The third comment consisted of a report by a panel of scientific experts who evaluated evening primrose oil as a dietary supplement and concluded that it was safe. The comment stated that the report on the safety of evening primrose oil should aid FDA in determining the GRAS status of Fuji's product because evening primrose oil is chemically related to both safflower and sunflower oils in that the primary constituent of all these oils is the GRAS substance linoleic acid. The comment stated that it was submitted because FDA must consider chemically and pharmacologically related substances in the diet when considering the GRAS status of any substance (§ 170.3(i)(2)).

The safflower and sunflower oils the petitioner proposed to use as raw material for the production of cocoa butter substitute are derived from high-oleic variant seeds containing approximately 75 percent oleic acid in their triglycerides instead of linoleic acid, which is the major fatty acid in evening primrose oil and in oils derived from traditional safflower and sunflower. Thus, the assertion that evening primrose oil is similar to high-oleic safflower and sunflower oils based on fatty acid content is erroneous.

More importantly, the petition does not seek to affirm the GRAS status of safflower oil and sunflower oil, both of which are common food items, but rather cocoa butter substitute derived by chemical processes from high-oleic safflower or sunflower oil. For these reasons, the agency finds this comment not relevant to the question of whether cocoa butter substitute derived from high-oleic safflower or sunflower oil is GRAS.

VIII. Conclusions

Based on the published literature about the petitioned cocoa butter substitute and the data supporting the safety of cocoa butter substitute from palm oil, corroborated by widely available information about the safe consumption of glycerol and of oleic and stearic acids, the agency concludes that cocoa butter substitute from high-oleic safflower or sunflower oil is GRAS when used in accordance with CGMP (21 CFR 184.1(b)(1)).

IX. Environmental Effects

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

X. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is significant if it meets any one of a number of specific conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or raising novel legal or policy issues. The Regulatory Flexibility Act requires agencies to minimize the economic impact of their regulations on small businesses.

FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. The rule does not raise novel legal or policy issues. The compliance cost to firms currently in the industry is zero because the rule prohibits no current activity. Potential benefits of the rule include the wider use of this cocoa butter substitute because of reduced uncertainty concerning its regulatory status, and any resources saved by eliminating the need to prepare further petitions to affirm the GRAS status of the use of this cocoa butter substitute.

Finally, in compliance with the Regulatory Flexibility Act, FDA certifies that the final rule will not have a significant economic impact on a substantial number of small businesses. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

XI. Effective Date

As this rule recognizes an exemption from the food additive definition in the Federal Food, Drug, and Cosmetic Act, and from the approval requirements applicable to food additives, no delay in effective date is required by the Administrative Procedure Act (5 U.S.C 553(d)). The rule will therefore be effective immediately (5 U.S.C. 553(d)(1)).

XII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Winter, G., ''A New Safflower Oil with a Low Iodine Value,'' *Nature*, 179:582–583, 1957.

2. Knowles, P. F., A. B. Hill, and J. E. Ruckman, ''High Oleic Acid Content in New Safflower, UC–1,'' *California Agriculture*, p. 15, 1965.

3. Fick, G. N., ''Genetics and Breeding of Sunflower,'' *Journal of the American Oil Chemists' Society*, 60:1252–1253, 1983.

4. Purdy, R. H., ''Oxidative Stability of High Oleic Sunflower and Safflower Oils,'' *Journal of the American Oil Chemists' Society*, 62:523–525, 1985.

5. Smith, J. R., ''Safflower: Due for a Rebound,'' *Journal of the American Oil Chemists' Society*, 62:1286–1291, 1985.

6. Purdy, R. H., ''High Oleic Sunflower: Physical and Chemical Characteristics,'' *Journal of the American Oil Chemists' Society*, 63:1062–1066, 1986.

7. Anonymous, ''U. S. Sun Crop: Potential Still not Realized,'' *Journal of the American Oil Chemists' Society*, 63:1218–1224, 1986.

8. Faulkner, R. W., ''Cocoa Butter Equivalents are Truly Specialty Vegetable Fats,'' *The Manufacturing Confectioner*, pp. 56–61, 1981.

9. Memorandum from M. DiNovi, FDA to L. Lin, FDA, November 2, 1988.

10. Feuge, R. O. et al., ''Cocoa Butter-Like Fats from Domestic Oils,'' *Journal of the American Oil Chemists' Society*, 35:194–199, 1958.

11. Lehninger, A. L., *Principles of Biochemistry*, Worth Publishers, Inc., New York, NY, 1982.

12. Memorandum from J. C. Griffiths, FDA to L. Lin, FDA, July 14, 1989.

13. Shimoda, T. et al., ''Safety Studies of a Transesterified Fat Produced by an Immobilized Lipase: I. Acute Oral Toxicity Study in Rats,'' *Journal of the American College of Toxicology*, 13 (Suppl. 1):10–18, 1994.

14. Shimoda, T. et al., ''Safety Studies of a Transesterified Fat Produced by an Immobilized Lipase: II. Subchronic Oral Toxicity and Recovery Studies in Rats,'' *Journal of the American College of Toxicology*, 13 (Suppl. 1):19–37, 1994.

15. Shimoda, T. et al., ''Safety Studies of a Transesterified Fat Produced by an Immobilized Lipase: III. Bacterial Reversion Test,'' *Journal of the American College of Toxicology*, 13 (Suppl. 1):38–45, 1994.

16. MacRae, A. R., ''Lipase-Catalysed Interesterification of Oils and Fats,'' *Journal of the American Oil Chemists' Society*, 60:291–294, 1983.

List of Subjects in 21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. Section 184.1259 is amended by revising the section heading and paragraph (a) to read as follows:

§ 184.1259 Cocoa butter substitute.

(a) The common or usual name for the triglyceride 1-palmitoyl-2-oleoyl-3-stearin is ''cocoa butter substitute primarily from palm oil.'' The common or usual name for the triglyceride 1-3-distearoyl-2-olein is ''cocoa butter substitute primarily from high-oleic safflower or sunflower oil.''

(1) The ingredient 1-palmitoyl-2-oleoyl-3-stearin is manufactured by:

(i) Directed esterification of fully saturated 1,3-diglycerides (derived from palm oil) with the anhydride of food-grade oleic acid in the presence of the catalyst trifluoromethane sulfonic acid (§ 173.395 of this chapter), or

(ii) By interesterification of partially saturated 1,2,3-triglycerides (derived from palm oil) with ethyl stearate in the presence of a suitable lipase enzyme preparation that is either generally recognized as safe (GRAS) or has food additive approval for such use.

(2) The ingredient 1-3-distearoyl-2-olein is manufactured by interesterification of partially unsaturated 1,2,3-triglycerides (derived from high-oleic safflower or sunflower oil) with ethyl stearate or stearic acid in the presence of a suitable lipase enzyme preparation that is either GRAS or has food additive approval for such use.

* * * * *

Dated: June 13, 1996.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–17542 Filed 7–9–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Boehringer Ingelheim Animal Health, Inc. The supplemental ANADA provides for the subcutaneous use of oxytetracycline injection in cattle for treatment of diseases caused by oxytetracycline susceptible organisms.

EFFECTIVE DATE: July 10, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506, has filed supplemental ANADA 200–008, which provides for subcutaneous use of oxytetracycline injection in addition to the approved intravenous and intramuscular use in beef and nonlactating dairy cattle for the treatment of pneumonia and shipping fever associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresi*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline. The product is also approved for intramuscular use in swine.

Boehringer Ingelheim's supplemental ANADA 200–008 for subcutaneous use of oxytetracycline injection (OXY–TET 200/BIO–MYCIN 200) in cattle is approved as of May 22, 1996, and the regulations are amended in 21 CFR 522.1660 (c)(1)(iii) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).