

Association, and The Georgia Industrial Gas Group
 ANR Pipeline Company
 United Gas Pipe Line Company
 El Paso Natural Gas Company
 Tennessee Gas Pipeline Company, a Division of Tenneco, Inc., and Midwestern Gas Transmission Company
 Northern Illinois Gas Company
 Great Lakes Gas Transmission Company
 Texas Gas Transmission Corporation
 Southern California Gas Company and Pacific Lighting Gas Supply Company
 Consumers Power Company
 Southwest Gas Corporation, Arizona Public Service, Company, Southern Union Gas Company and Gas Company of New Mexico
 MIGC, Inc.
 Mississippi River Transmission Corporation
 Consolidated Edison Company of New York, Inc.
 The Brooklyn Union Gas Company
 Transcontinental Gas Pipe Line Corporation
 Panhandle Eastern Pipe Line Company and Trunkline Gas Company
 Texas Eastern Transmission Corporation
 Northwest Energy

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DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 134

[T.D. 84-127]

Customs Regulations Amendments Relating to Country of Origin Marking

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

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations to establish certification requirements to prohibit the concealment of country of origin information appearing on marked articles imported in bulk and repacked in the United States after release from Customs custody. Importers will be required to certify to the district director having custody of the articles that: (a) If the importer does the repacking, he must not obscure or conceal the country of origin marking information appearing on the article, or else the container (e.g., blister pack) must be marked in accordance with applicable law and regulations; or (b) if the article is sold or transferred, the importer must notify the subsequent purchaser or repacker, in writing, at the time of sale or transfer, that any repacking of the article must conform to the marking requirements. The purpose of the change is to ensure that an ultimate purchaser in the United States is aware of the country of origin of the article.

EFFECTIVE DATE: This document is effective on July 2, 1984.

FOR FURTHER INFORMATION CONTACT: Harold Loring, Entry, Licensing and Restricted Merchandise Branch, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229 (202-566-5765).

SUPPLEMENTARY INFORMATION: Section 304, Tariff Act of 1930, as amended (19 U.S.C. 1304), provides that, unless expressly excepted, every article of foreign origin (or its container) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the article or container will permit, in such manner as to indicate to an ultimate purchaser, the English name of the country of origin of the article.

Section 304(c) provides that any article not marked as required, shall be subject to a duty of 10 percent ad valorem, in addition to any other duty imposed by law and whether or not the article is exempt from the payment of ordinary Customs duties, unless the article is exported, destroyed, or marked, under Customs supervision. These marking duties cannot be remitted, wholly or in part.

In addition to the requirement for marking duties under section 304(c) for country of origin marking violations, civil penalties may be incurred by the importer under section 592, Tariff Act of 1930, as amended (19 U.S.C. 1592), for entering merchandise into the domestic commerce by means of false documents; and criminal sanctions may be assessed under 18 U.S.C. 1001 for presenting false and misrepresented documents to the Government in connection with an entry. Criminal sanctions also may be assessed under 19 U.S.C. 1304(e) for concealing or obscuring country of origin markings. Further, if merchandise released from Customs custody under a bond is found not to be legally marked, liquidated damages also may be assessed for breach of the bond conditions.

Part 134, Customs Regulations (19 CFR Part 134), sets forth the country of origin marking requirements of 19 U.S.C. 1304, as well as the consequences and procedures to be followed if imported articles are not legally marked.

It has been brought to Customs attention by the Hand Tools Institute, an association consisting of domestic producers of hand tools, that various foreign-made tools are entering the United States in bulk containers, properly marked with the country of origin. Once in the United States however, these tools are repacked in sealed, unmarked blister packs in such a

manner that the country of origin marking appearing on the article is concealed from view, i.e., by placing the article marked side down against the cardboard in a blister pack. Samples have been submitted to Customs showing this deceptive practice which is not limited to the repacking of hand tools, but extends to other imported products as well.

The intent of the marking legislation since the first enactment appeared as section 6 of the Tariff Act of 1980, has been to allow the ultimate purchaser in the United States to know the country of origin of foreign articles. By knowing the country of origin, it allows the purchaser to make an informed choice on whether to buy the foreign article or its domestic counterpart. This choice was provided in large part because Congress recognized that if given a choice, consumers prefer domestic goods. To conceal or obscure country of origin marking information prevents consumers from exercising this preference; denies domestic producers the benefit flowing from such consumer preference; and frustrates the Congressional will.

In a related matter, by T.D. 83-155 published in the *Federal Register* on July 26, 1983 (48 FR 33860), Customs amended its regulations by adding a new section 134.25 to provide for certification requirements for importers with respect to certain *unmarked* articles (i.e., J-list articles and articles incapable of being marked) imported in bulk and repacked in the United States after release from Customs custody. Customs believes that similar requirements should be adopted with respect to repacked *marked* articles, based on the same rationale. That is, if Customs knows, or has reason to believe that the marked articles will not reach the ultimate purchaser in such a condition as to enable the purchaser to know the country of origin of the article before purchase, the Customs cannot find the marking of the article to satisfy the requirements of the statute. See *U.S. Wolfson Bros. Corp. v. United States*, 52 CCPA 46, C.A.D. 856 (1965), upon which this rationale is based.

Accordingly, to minimize the practice of concealing country of origin information appearing on repacked marked articles, by notice published in the *Federal Register* on July 26, 1983 (48 FR 33908), Customs proposed to require importers to certify to the district director having custody of articles that: (a) If the importer does the repacking, he must not obscure or conceal the country of origin marking information appearing on the article, or else the container (e.g.,

blister pack) must be marked in accordance with applicable law and regulations; or (b) if the article is sold or transferred, the importer must notify the subsequent purchaser or repacker, in writing, at the time of sale or transfer, that any repacking of the article must conform to the marking requirements.

Although the certification requirements are written in the disjunctive, *i.e.*, either the certifier will mark if he repacks or notify his transferee if the certifier does not repack, if a certifier repacks and marks the new containers and resells, but the merchandise is such that his transferee is also likely to repack further, then the certifier must also notify his transferee of the marking requirements.

The purpose of the proposed certification requirements are to place the responsibility on the importer to ensure, as best as possible, that the country of origin information reaches the ultimate purchaser in such a manner as to enable the purchaser by an inspection of the article (or its container) to know the country of origin of which the article is a product before he chooses to purchase it.

As now indicated in new subsection (f), the certification requirements will not apply to those situations where a marked article is repacked in an unmarked container that can readily be opened for inspection by the ultimate purchaser in United States. See, for instance, the analogous situation presented in 19 CFR 134.24(d)(3) in which disposable *unsealed* containers need not be marked if imported filled with a marked article and the container is normally opened by the ultimate purchaser prior to purchase. Of course, if such a container bears a U.S. address, then the country of origin of the contents must appear on the container in comparable size and in close proximity to the U.S. address in accordance with 19 CFR 134.46. This latter regulation is designed to avoid confusion in the mind of an ultimate purchaser and will now apply to container packaging added in the United States to repackage imported *marked* articles.

It should be emphasized that, under the new certification requirements, the importer who does not repack would not be liable to Customs if his transferee who does repack failed to comply with the marking requirements, provided that the importer follows through on his certification by informing the repacker of such requirements. If it is determined that the importer took the proper action according to his certification in this regard and the repacker failed to comply, Customs could seek criminal action against the repacker under 19

U.S.C. 1304(e). In addition, the certification and proof of compliance also may be useful in a civil action brought against a repacker under 15 U.S.C. 1125.

It should also be emphasized that a broker who files an entry as importer of record, posting his own bond, is liable pursuant to section 134.26(e) for marking duties and penalties if the actual owner fails to fulfill the certification requirements, at least until a superseding bond and actual owners declaration are filed under 19 CFR 141.20. This is also the position Customs has taken with respect to the general repackaging certification contained in 19 CFR 134.25; as established by T.D. 83-155 published in the *Federal Register* on July 26, 1983 (48 FR 33860).

In addition to these new certification requirements, Customs is reinstating former § 134.34, Customs Regulations (19 CFR 134.34), relating to certain repacked articles that are excepted from marking requirements. This section was inadvertently repealed when Customs enacted § 134.25. It was erroneously believed that these two sections overlapped and therefore § 134.34 was no longer necessary. However, after further review, it has been determined that this is no longer the case because § 134.34 relates to the repacking under Customs guidance of certain unmarked articles subject to special exemptions, *i.e.*, semi-conductors, whereas § 134.25 relates to the repacking of J-list articles and articles incapable of being marked.

Discussion of Comments

Of the forty-two comments received in response to the notice, thirty-eight favored the proposal and four were opposed. One opposing commenter stated that this proposal was duplicative of what he believed was the Federal Trade Commission's (FTC) role to police misrepresentation with respect to packed goods. Customs does not agree. In the case of *L. Heller & Son v. Federal Trade Commissioner*, 191 F.2d 954 (7th Cir. 1951) the court recognized that 19 U.S.C. 1304 and section 5 of the Federal Trade Commission Act are not repugnant. The court stated that 19 U.S.C. 1304 was "concerned solely with the extent to which the Treasury Department, incidentally to its collection of Customs duties, should regulate the labeling of imported goods."

A similar comment in opposition criticized the rule on the ground that if the individual goods are marked on importation then the requirements of 19 U.S.C. 1304 are met, and Customs' role is at an end. This view is not in accord with *U.S. Wolfson Bros. Corp. v. United States*, 52 C.C.P.A. 46, C.A.D. 856 (1965),

which recognized that, if Customs knows or has reason to believe that the marked articles will not reach the ultimate purchaser in such a condition as to enable the purchaser to know the country of origin of the article before purchase, then Customs cannot find the marking of the article to satisfy the requirements of 19 U.S.C. 1304. The same commenter also recommended that the violative practice of concealing country of origin marking by deceptive repackaging be attacked under existing regulation and law rather than imposing the certification requirements upon all importers who import bulk goods that will be repacked. Customs believes existing regulations are insufficient to remedy this problem as 19 U.S.C. 1304(e) is a criminal statute the violation of which requires "intent" for there to be a criminal prosecution. The proposed certification requirements will enable Customs to remedy the situation without necessitating a criminal prosecution requiring intent.

Another commenter opposed the rule on the ground that it is misplaced, *i.e.*, the rule as proposed will become subsection (c) in 19 CFR 134.13, which only applies to articles repacked in bonded warehouses, manipulated under 19 U.S.C. 1562, or manipulated in a foreign trade zone. Thus, the subsection as proposed, would not apply to repacking accomplished in a private non-bonded warehouse. To avoid this result, proposed § 134.13(c) will be a new § 134.26.

The same commenter stated that the certification requirements are too burdensome *i.e.*, an importer may have to certify an entire entry containing many articles, only a few of which will be repacked. The commenter also suggested that stronger language be added to the General Term Bond instead. Customs does not agree. Blanket certification, as suggested in the proposed rule, may be drawn to resolve these problems. Blanket notification procedures, however, have not yet been approved by Customs.

Finally, one commenter believed the proposal was too broad. He suggested that the language should be changed to exempt containers which will not be sealed so that the ultimate purchaser can inspect the marked article inside. As previously stated in this document, Customs agrees. The rule will not apply to this kind of situation.

E.O. 12291

It has been determined that the amendments in this document are not a "major rule" within the criteria provided in section 1(b) of E.O. 12291, and

therefore no regulatory impact analysis is required.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 603, 604) are not applicable to these amendments because the rule will not have a significant economic impact on a substantial number of small entities.

Accordingly, the document contains a certification pursuant to section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that the amendments will not have a significant economic impact on a substantial number of small entities.

Drafting Information

The principal author of this document was Glen E. Vereb, Regulations Control Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Part 134

Customs duties and inspection, Imports, Importers, Labeling, Packaging, and Containers.

Regulations Amendments

Part 134, Customs Regulations (19 CFR Part 134) is amended as set forth below:
William von Raab,
Commissioner of Customs.

Approved:
John M. Walker, Jr.,
Assistant Secretary of the Treasury.
May 14, 1984.

PART 134—COUNTRY OF ORIGIN MARKING

Part 134, Customs Regulations (19 CFR Part 134), is amended by adding a new § 134.26 to read as follows:

§ 134.26 Imported articles repacked or manipulated.

(a) *Certification requirements.* If an article subject to these requirements is intended to be repacked in retail containers (e.g., blister packs) after its release from Customs custody, or if the district director having custody of the article, has reason to believe such article will be repacked after its release, the importer shall certify to the district director that: (1) If the importer does the repacking, he shall not obscure or conceal the country of origin marking appearing on the article, or else the new container shall be marked to indicate the country of origin of the article in accordance with the requirements of this Part; or (2) if the article is intended to be sold or transferred to a subsequent

purchaser or repacker, the importer shall notify such purchaser or transferee, in writing, at the time of sale or transfer, that any repacking of the article must conform to these requirements. The importer, or his authorized agent, shall sign the following statement.

Certificate of Marking by Importer—Repacked Articles Subject to Marking

(Port of entry) _____
I, _____ of _____, certify that if the article(s) covered by this entry (entry no.(s) _____ dated _____), is (are) repacked in retail container(s) e.g., blister packs, while still in my possession, the new container(s) will not conceal or obscure the country of origin marking appearing on the article(s), or else the new container(s), unless excepted, shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the container(s) will permit, in such manner as to indicate the country of origin of the article(s) to the ultimate purchaser(s) in accordance with the requirements of 19 U.S.C. 1304 and 19 CFR Part 134. I further certify that if the article(s) is (are) intended to be sold or transferred by me to a subsequent purchaser or repacker, I will notify such purchaser or transferee, in writing, at the time of sale or transfer, of the marking requirements.
Date _____
Importer _____

The certification statement may appear as a typed or stamped statement on an appropriate entry document or commercial invoice, or on a preprinted attachment to such entry or invoice; or it may be submitted in blanket form to cover all importations of a particular product for a given period (e.g., calendar year). If the blanket procedure is used, a certification must be filed at each port where the article(s) is entered.

(b) *Facsimile signatures.* The certification statement may be signed by means of an authorized facsimile signature.

(c) *Time of filing.* The certification statement shall be filed with the district director at the time of entry summary. If the certification is not available at that time, a bond shall be given for its production in accordance with § 141.66, Customs Regulations (19 CFR 141.66). In case of repeated failure to timely file the certification required under this subsection, the district director may decline to accept a bond for the missing document and demand redelivery of the merchandise under § 134.51, Customs Regulations (19 CFR 134.51).

(d) *Notice to subsequent purchaser or repacker.* If the article is sold or transferred to a subsequent purchaser or repacker the following notice shall be given to the purchaser or repacker:

Notice to Subsequent Purchaser or Repacker

These articles are imported. The requirements of 19 U.S.C. 1304 and 19 CFR

part 134 provide that the articles on their containers must be marked in a conspicuous place as legibly, indelibly and permanently as the nature of the article or container will permit, in such a manner as to indicate to an ultimate purchaser in the United States, the English name of the country of origin of the article.

(e) *Duties and Penalties.* Failure to comply with the certification requirements in paragraph (a) may subject the importer to a demand for liquidated damages under § 134.54(a) and for the additional duty under 19 U.S.C. 1304. Fraud or negligence by any person in furnishing the required certification may also result in a penalty under 19 U.S.C. 1592.

(f) *Exceptions.* The requirements of this section do not apply to repackaging in a container that can readily be opened for inspection by the ultimate purchaser in the United States, unless such container bears a U.S. address or other potentially misleading marking.

Part 134, Customs Regulations (19 CFR Part 134), is further amended by adding a new § 134.34 to read as follows:

§ 134.34 Certain repacked articles.

(a) *Exception for repacked articles.* An exception under § 134.32(d) may be authorized in the discretion of the district director for imported articles which are to be repacked after release from Customs custody under the following conditions:

(1) The containers in which the articles are repacked will indicate the origin of the articles to an ultimate purchaser in the United States.

(2) The importer arranges for supervision of the marking of the containers by Customs officers at the importer's expense or secures such verification, as may be necessary, by certification and the submission of a sample or otherwise, of the marking prior to the liquidation of the entry.

(b) *Liquidation of entries.* The liquidation of such entries may be deferred for a period of not more than 60 days from the date that a request for repacking is granted. Extensions of the 60-day deferral period may be granted by the district director in his discretion upon written application by the importer.

(R.S. 251, as amended (19 U.S.C. 66), section 304, 624, 46 Stat. 731, as amended, 759 (19 U.S.C. 1304, 1624), 77A Stat. 14 (19 U.S.C. 1202))

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BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 184****[Docket No. 76G-0488]****Direct Food Substances Affirmed as Generally Recognized as Safe; Cocoa Butter Substitute Primarily From Palm Oil****AGENCY:** Food and Drug Administration.**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing the term "cocoa butter substitute primarily from palm oil" as the common or usual name for 1-palmitoyl-2-oleoyl-3-stearin. The agency is also revising the regulation that affirms this substance as generally recognized as safe (GRAS) to make clear that cocoa butter substitute primarily from palm oil is not to be used as an ingredient in standardized foods unless permitted by individual standards of identity. This action is based on comments received regarding the common or usual name of this substance.

EFFECTIVE DATE: July 1, 1985.

Compliance may begin June 1, 1984, and labeling of all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1985, shall comply.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (formerly Bureau of Foods) (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0177.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of November 21, 1978 (43 FR 54238), FDA published a final rule that affirmed 1-palmitoyl-2-oleoyl-3-stearin as GRAS and temporarily listed this substance under the name "cocoa butter substitute from palm oil." That final rule also granted 60 days for additional comments on the common or usual name of this substance. FDA later extended the comment period until February 21, 1979 (44 FR 6706; February 2, 1979). FDA received comments on the common or usual name from 16 persons, including a consumer, a trade association, a consultant, the petitioner for affirmation of GRAS status, and manufacturers. The comments received on the common or usual name and FDA's responses are as follows:

1. A few comments cited FDA's proposal of September 19, 1978, dealing with cheese substitutes (43 FR 42118), and stated that in other actions, FDA

has required that a substitute possess similar physical and organoleptic properties to the food simulated. These comments argued that use of the term "cocoa butter substitute" as part of the common or usual name of 1-palmitoyl-2-oleoyl-3-stearin would be inappropriate because the product does not have the same physical characteristics as cocoa butter. These comments also argued that this substitute varies considerably from cocoa butter in its physical and organoleptic properties. The comments stated that these differences might change the taste of products made using the substitute in place of cocoa butter. Other comments, however, described the product as a suitable substitute for cocoa butter in confectionary products and described its functional similarities to cocoa butter in terms of its working characteristics. One comment stated that testing of the product had demonstrated that, using a milk chocolate recipe, candy made with the substitute could not be distinguished by taste from that made with cocoa butter.

FDA advises that the criterion that it proposed in the September 19, 1978 document (43 FR 42121) for substitutes for milk, cream, and cheese was "reasonable similarity." The agency did not propose to require that a substitute food be identical to the food for which it substitutes; only that it be reasonably similar in the characteristics that are most pertinent to the usual and normal uses of the food. The pertinent characteristics that FDA considered in the September 19, 1978 document were that the substitute food should be nutritionally equivalent to the traditional food and should have similar levels of fat and moisture, as well as similar physical attributes such as color, body, and texture.

1-Palmitoyl-2-oleoyl-3-stearin is reasonably similar to cocoa butter in the characteristics that are most pertinent to cocoa butter's use in confections, soft candy, and sweet sauces and toppings. As FDA stated in the *Federal Register* of November 21, 1978 (43 FR 54238), cocoa butter substitute possesses the same or similar melting point, solids profile, and palatability as cocoa butter. The comments do not provide information that would justify a finding to the contrary. The differences between cocoa butter and the substitute that are reported in the comments are slight or moderate differences in physical and chemical characteristics that have not been shown to modify the value of the substitute when it is used in place of cocoa butter as a food ingredient. The comments also do not provide any basis for concluding that use of the substitute would change the taste of foods if the

substitute is used in place of cocoa butter. In fact, two comments stated that use of the substitute to replace cocoa butter in a product did not produce discernible taste differences.

Therefore, based on the comments and on the administrative record, FDA concludes that the substitute is reasonably similar to cocoa butter, and that it consequently is a cocoa butter substitute for the food ingredient uses listed in 21 CFR 184.1259.

2. Several comments favored the name proposed in the November 21, 1978 document. A number of comments, however, opposed the establishment of "cocoa butter substitute from palm oil" as the common or usual name for 1-palmitoyl-2-oleoyl-3-stearin and presented a variety of opposing arguments. One of the most prevalent objections was to the use of the term "cocoa butter" in the name of the food. Several comments argued that the use of this term would mislead consumers by suggesting that the product could be used as an ingredient in all cocoa products. The comments on this aspect of the proposal pointed out that the product is not currently permitted as a replacement for cocoa butter in standardized cocoa products, and that this use is one of the most important for cocoa butter. Conversely, other comments were concerned that adoption of the term "cocoa butter substitute" would lead to changes in the standard of identity for cocoa products, and that the quality of standardized cocoa products would be adversely affected by the use of the substitute. Another comment stated that in order to be commercially successful, the petitioner would eventually seek modification of the standards of identity for chocolate, and that the adoption of the term "cocoa butter substitute" would make modification of the chocolate standard easier.

The agency disagrees with the suggestion that the term "cocoa butter substitute" is a misleading term. The agency recognizes that current standards of identity for cocoa products do not permit the use of the substitute product, but the fact that this product is not an appropriate substitute in all instances should not serve as a bar to the use of "cocoa butter substitute" as part of the name for this product. As discussed in response to comment 1, FDA finds, and this finding is supported by comments from manufacturers of confections, that this product is an appropriate substitute for cocoa butter in the manufacture of confections. The agency also has affirmed that this use of the product is GRAS (21 CFR 184.1259).

The use of the substitute in standardized cocoa products is a separate issue. The use of the substitute will not be permitted unless the standards of identity are amended to provide for its use. Such an amendment would require a separate proceeding under 21 U.S.C. 341 and 371(e), which provided interested persons with the opportunity to petition to amend standards of identity and to request a public hearing if the petition is denied. Any decision resulting from such a proceeding would be based on the record developed in that proceeding, and the prior designation of a particular ingredient as a "cocoa butter substitute" would not prejudice that decision.

3. A few comments stated that the term "cocoa butter substitute" should not be used as part of the common or usual name because it was too broad a term and refers to the potential use of the product rather than describing the basic nature of the product. Other comments stated generally that use of the term "cocoa butter substitute" obscures rather than makes clearer the basic nature of the food and its characterizing properties and ingredients.

Under 21 CFR 102.5, the common or usual name of a food must accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. In some cases, particularly for new foods, the best way to accomplish this goal is by making clear in the common or usual name of the food that it is a substitute for a specific traditional food. FDA finds that the immediate case is one such instance because this new ingredient's ability to be used in place of cocoa butter in certain foods is its most significant characteristic. Moreover, the primary objectives in establishing a common or usual name for this substance are (1) to differentiate it from cocoa butter and (2) to differentiate it from all other cocoa butter substitutes. Including the word "substitute" in the name will adequately inform consumers that this substance is not cocoa butter. Declaration of the principal starting material (palm oil) in the name will fulfill the second objective.

4. One comment disputed FDA's authority to establish a common or usual name that utilizes the name of a traditional food. This comment asserted that FDA only has statutory authority to regulate adulteration and misbranding, and that by proposing to establish the name at issue here, FDA is seeking to give statutory lawfulness to the misbranding and adulteration that

would result if this product is substituted for cocoa butter.

FDA disagrees with this comment. The agency has the legal authority to establish a common or usual name for this food ingredient. Under 21 U.S.C. 371(a), FDA has authority to adopt regulations for the efficient enforcement of the Federal Food, Drug, and Cosmetic Act (the act). The regulation establishing the common or usual name for this cocoa butter substitute contributes to the efficient enforcement of three sections of the act: Section 403(i)(1) (21 U.S.C. 343(i)(1)), which provides that a food shall be deemed to be misbranded unless its label bears the common or usual name of the food, if one exists; section 403(a) (21 U.S.C. 343(a)), which provides that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular; and section 201(n) (21 U.S.C. 321(n)), which provides that in determining whether the labeling of a product is misleading, it is necessary to consider, among other factors, the extent to which the labeling fails to reveal a material fact. This regulation fulfills the purposes and requirements of these provisions by ensuring that the common or usual name for this cocoa butter substitute provides basic information about the identity of this ingredient, as well as other material facts (see response to comment 3) that are needed to prevent consumer confusion and deception. FDA's authority to adopt common or usual name regulations was upheld in *American Frozen Food Institute v. Mathews*, 413 F. Supp. 548 (D.D.C. 1976), *aff'd sub nom. American Frozen Food Institute v. Califano*, 555 F.2d 1059 (D.C. Cir. 1977). The fact that the common or usual name established by this regulation utilizes the name of a traditional food does not constitute an infirmity. As explained in response to comment 3, the common or usual name makes clear that 1-palmitoyl-2-oleoyl-3-stearin is not cocoa butter but a substitute for it. Thus, it distinguishes the substitute from cocoa butter, thereby preventing consumer confusion. In sum, the agency finds that the comment is without merit.

5. One comment stated that the substance has not been thoroughly tested, and that its use may result in an inferior product if substituted for cocoa butter in some uses of that ingredient.

FDA acknowledges that further testing of the substitute in various applications might reveal differences that would lead manufacturers to conclude that the substitute cannot replace cocoa butter in all of its uses. However, the common or usual name

still adequately describes the basic nature of the food because this product is reasonably similar to, and in many instances can be used as a substitute for, cocoa butter.

6. One comment objected to the use of the term "cocoa butter substitute" on the grounds that cocoa butter is sold for use as protection against and relief of sunburn, windburn, and chapped hands and for body massage and other skin care applications. The comment asserted that adoption of the proposed name would constitute tacit approval of the substitute as a replacement for cocoa butter in these nonfood uses.

FDA is neither approving nor disapproving the use of the substitute as a replacement for cocoa butter in foods, drugs, or cosmetics. The agency has affirmed that the substance is GRAS for use in the foods that it identified in the GRAS affirmation regulation and is now only establishing a common or usual name for that substance. The agency is confident that manufacturers are aware of their responsibilities when using new ingredients in drug and cosmetic formulations, and that the establishment of this common or usual name will not result in confusion as to the uses for which this product has been approved.

7. A number of comments stated that in accordance with § 101.4(b)(4) and Part 102 (21 CFR 101.4(b)(4) and Part 102), the nomenclature for this product must reflect that it is a synthetic product obtained through esterification and derived from fully hydrogenated palm oil, food-grade oleic anhydride, and glycerol. One of the comments stated that the proposed name does not conform to the requirements of § 101.4(b)(14) because the name does not include the degree of hydrogenation of this fat.

The agency disagrees with these comments. The requirements of § 101.4 involve the listing of specific fats and oils in an ingredient statement and do not apply to the product 1-palmitoyl-2-oleoyl-3-stearin or to the designation of a common or usual name for this product. For products that are a blend of fats and oils, § 101.4(b)(14) requires that the ingredient statement list the name of the blend (e.g., "hydrogenated vegetable oil") and the names of each of the fats and oils in the blend. However, 1-palmitoyl-2-oleoyl-3-stearin is not simply a mixture of fats and oils and does not contain ingredients in the traditional sense. The substitute is synthesized by chemically combining diglycerides derived from palm oil with the anhydride of food-grade oleic acid. The resulting product is structurally different from the substances from

which it is derived and cannot be described as a blend. Therefore, adoption of a name that includes the starting materials of this substance is inappropriate, and the provisions of § 101.4(b)(14) are not applicable.

In addition, including a list of starting materials in the common or usual name would make the name long, complicated, and difficult for consumers to understand. Those commenting did not articulate any benefits that would compensate for these disadvantages of declaring the starting materials.

Finally, for the reasons set forth in response to comment 3, the common or usual name that the agency is adopting complies with 21 CFR Part 102.

8. A number of comments objected to the proposed name "cocoa butter substitute from palm oil" because it implies that the product is derived entirely from palm oil. These comments argue that this name consequently is misleading.

FDA agrees. The final rule, therefore, changes the name of this substance to "cocoa butter substitute primarily from palm oil."

9. One comment stated that the name should include either the term "synthetic" or "artificial" to inform consumers that the product is manufactured by chemical synthesis.

The agency concludes that the name "cocoa butter substitute primarily from palm oil" is more informative to consumers than the terms "synthetic" or "artificial" because the latter terms imply equivalence to cocoa butter and may, therefore, mislead consumers into believing that the substitute is an exact duplicate of cocoa butter. Although it is not an exact duplicate, this substance is sufficiently similar to cocoa butter that it may be used as a substitute in appropriate products.

10. Two comments stated that if the proposed name were adopted, those who adhere to the Jewish and Islamic dietary requirements and those who are vegetarians would not be informed of the possible animal origins of the oleic acid and glycerol components of the products.

The agency recognizes that even though animal fat is not directly added as an ingredient of this product, some consumers may consider the substitute to be derived from animal products if the oleic acid and glycerol starting materials are derived from animal sources. However, the agency traditionally has not required that the possible animal derivation of substances such as oleic acid or glycerol be indicated in the label declaration of these ingredients, and FDA does not believe that it would be appropriate to deviate from this

traditional policy in this rulemaking. Nonetheless, the agency has modified the name of the substitute not only for the reason set forth in paragraph 8 but also to ensure that the name alerts consumers to the fact that this product may not be of strictly vegetable origin.

FDA believes that because the name now states that this substance is primarily from palm oil, interested consumers will investigate the other sources of this cocoa butter substitute before they purchase any food in which it is an ingredient.

11. One comment stated that the common or usual name should reflect the fact that this product has been esterified because many countries have laws that prohibit the esterification of fats, and the name should include sufficient information about its processing to enable commercial users to comply with the laws of foreign countries.

The agency believes that manufacturers have sufficient access to processing information to enable them to determine whether the product meets the criteria that foreign governments apply to foods that are intended for import into their countries. Therefore, the agency does not consider it necessary to adopt a common or usual name that includes processing methods that have little or no meaning to the average consumer.

12. A variety of other names were offered by those commenting as alternatives to the common or usual name proposed. One name suggested was "modified oil from palm oil and oleic acid for confectionary," with the words "for confectionary" optional. Another name suggested was "hydrogenated vegetable oil made from partially hydrogenated palm kernel oil and/or — oils," with the blank to be filled in with the name of any other oils that are used. Still another name suggested was the use of a fanciful name followed in parenthesis by "a synthetic fat obtained from fully hydrogenated palm oil, oleic anhydride from — and glycerol from —," with the blanks to be filled in by the source of the oleic acid derivative and the glycerol. Another comment suggested simply "— vegetable butter," with a fanciful name to be included in the blank. Another comment suggested "noncocoa butter vegetable fat" as the common or usual name for this product.

FDA has reviewed the variety of names suggested for this product and has concluded that none of the names offered as alternatives describe the product as clearly or as succinctly as that established by this final rule. As

discussed elsewhere in this document, FDA has concluded that it is not necessary to disclose in the common or usual name all of the starting materials used to make this product because the product does not bear any resemblance to the starting materials. A list of starting materials would not be meaningful to consumers and would likely mislead them into believing that such starting materials are actually ingredients of this product. In the case of "noncocoa butter vegetable fat," the name expresses what the product is not, rather than what the product is. The term "— vegetable butter" is not descriptive enough of the characterizing properties of this product.

13. A few comments were concerned that the establishment of a common or usual name such as "cocoa butter substitute" will lead to a proliferation of names that merely declare the substance to be a substitute for the traditional food. For example, one of these comments asked whether horsemeat could be labeled as "pork substitute from horseflesh," and two comments pointed out that FDA would not permit margarine to be labeled as "dairy butter substitute." Another comment asked that FDA define the criteria that it will use in deciding whether to permit other fats that are used as cocoa butter substitutes to be labeled as such. These comments stated that there was no apparent restriction as to what could be designated as a "substitute," which could lead to inferior ingredients being used in confectionary products.

The act requires that if a food ingredient has a common or usual name, it must be declared by that name (21 U.S.C. 343(i)(1)). Thus, horsemeat must be labeled as horsemeat and margarine labeled as margarine. However, in the case of a new food, the criteria that the agency applies in deciding whether the degree of similarity that exists between that food and an old food justifies naming it as a substitute for the old food is the same type of criteria that FDA has applied in this case. The two foods should have the same or similar working properties; have reasonable similar physical characteristics, such as melting point, solids profile, and palatability; and produce reasonably similar organoleptic properties in the foods to which they are added.

14. One comment stated that no analytical methods are available to differentiate between products made using cocoa butter and those made using the substitute, and that, therefore, a substitution in a standardized chocolate product could not be detected.

FDA acknowledges that a substitution could occur in a standardized chocolate product. However, such a substitution can be made irrespective of the name of the food ingredient. FDA uses means other than the establishment of a common or usual name to determine whether a standardized food has been adulterated by the addition of an ingredient not provided for in the food standard. These means include factory inspections and examination of inventory data for raw materials. Thus, FDA finds this comment to be irrelevant to the question of the appropriate common or usual name for 1-palmitoyl-2-oleoyl-3-stearin.

15. The November 21, 1978 final rule affirming this ingredient as GRAS described the procedure by which any person adversely affected by that rule could request a hearing concerning the GRAS status of the substitute. One manufacturer requested a hearing if the common or usual name was not changed but did not challenge the GRAS status of the product.

FDA is denying this request for a hearing because the agency is not required to hold a hearing on either the question of the appropriate common or usual name of a substance or the question of whether a substance should be affirmed as GRAS. Neither the determination of GRAS status nor the determination of common or usual name is made under the formal rulemaking provisions of the act. (The formal rulemaking provisions are 21 U.S.C. 348 and 371(e).) FDA erred in offering a hearing on the GRAS status of this substance in the first place and hereby withdraws that offer.

16. Although not requested by comments, FDA is amending 21 CFR 184.1259(a) by adding an affirmative statement that the term "cocoa butter substitute primarily from palm oil" is the common or usual name for 1-palmitoyl-2-oleoyl-3-stearin. This change is necessary to prevent the possible misinterpretation that the scientific name could also be used as the common or usual name for this product on food labels. The agency advises that the ingredient must be uniformly designated in lists of ingredients on food labels through use of the established common or usual name. This change in the GRAS affirmation regulation is not substantive and therefore does not require publication of a new proposal. The agency is also making minor editorial changes in 21 CFR 184.1259(c) to update the language to be consistent with other recently published GRAS affirmation final rules.

FDA has carefully considered the potential environmental effects of this

action and concludes that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. A copy of the environmental assessment supporting this conclusion may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

This requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued before January 1, 1981, and is therefore exempt.

In accordance with Executive Order 12291, the agency has carefully analyzed the economic effects of this regulation, and the agency has determined that the final rule is not a major rule as defined by the Order. The agency's finding of no major economic impact and the evidence supporting this finding is contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

The agency periodically announces by notice in the Federal Register uniform effective dates for compliance with food labeling requirements. (See, for example, the Federal Register of August 13, 1982 (47 FR 35185).) That scheduling of the next effective date (July 1, 1985) will allow sufficient time for manufacturers to use up label stocks declaring the ingredient by other names and to schedule label revisions to coincide with other label revisions (that may be necessary for reasons that are unrelated to the establishment of this common or usual name) in order to minimize costs to industry and consumers.

List of Subjects in 21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 403, 701(a), 52 Stat. 1041 as amended, 1047-1048 as amended, 1055 (21 U.S.C. 321(n), 343, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 184 is amended in § 184.1259 by revising the section heading and paragraphs (a) and (c), to read as follows:

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

§ 184.1259 Cocoa butter substitute primarily from palm oil.

(a) The common or usual name for the triglyceride 1-palmitoyl-2-oleoyl-3-

stearin is "cocoa butter substitute primarily from palm oil." The ingredient is manufactured by 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).

(c) In accordance with § 184.1(b)(1), the ingredient is used in the following food categories at levels not to exceed current good manufacturing practice: Confections and frostings as defined in § 170.3(n)(9) of this chapter; coatings of soft candy as defined in § 170.3(n)(38) of this chapter; and sweet sauces and toppings as defined in § 170.3(n)(43) of this chapter; except that the ingredient may not be used in a standardized food unless permitted by the standard of identity.

Effective date. Compliance with this regulation may begin June 1, 1984, and labeling of all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1985, shall comply.

(Secs. 201(n), 403, 701(a), 52 Stat. 1041 as amended, 1047-1048 as amended, 1055 (21 U.S.C. 321(n), 343, 371(a)))

Dated: May 11, 1984.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 84-14632 Filed 5-31-84; 9:45 am]
BILLING CODE 4160-01-M

21 CFR Part 510

Animal Drugs, Feeds, and Related Products; Change of Sponsor Name

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name for several approved new animal drug applications (NADA's) from Feed Specialties Co. to Feed Specialties Co., Inc.

EFFECTIVE DATE: June 1, 1984.

FOR FURTHER INFORMATION CONTACT: John W. Borders, Center for Veterinary Medicine (formerly Bureau of Veterinary Medicine) (HFV-238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6243.

SUPPLEMENTARY INFORMATION: Central Soya Co., Inc., 1300 Fort Wayne Bank Bldg., Fort Wayne, IN 46802, has informed FDA that it has purchased the

assets of Feed Specialties Co., effective February 10, 1984. The firm will continue to operate as an independent entity. However, Central Soya has filed several supplemental NADA's reflecting a change of sponsor name to Feed Specialties Co., Inc. The NADA's for affected premixes are 97-289, tylosin; 107-957, tylosin and sulfamethazine; 118-877, pyrantel tartrate; 132-448, bambarmycins; 132-660, lincomycin; and 133-361, virginiamycin. This is an administrative change which does not in any other way affect the approval of the firm's NADA's. The agency is amending the regulations to reflect the change.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting requirements.

PART 510—NEW ANIMAL DRUGS

§ 510.600 [Amended]

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 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.83), § 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications is amended in paragraph (c)(1) in the entry for "Feed Specialties Co." by changing the firm name to read "Feed Specialties Co., Inc." and in paragraph (c)(2) in the entry for "017274" by changing the firm name "Feed Specialties Co." to read "Feed Specialties Co., Inc."

Effective date: June 1, 1984.

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

Dated: May 25, 1984.

William B. Bixler,

Associate Director for Surveillance and Compliance, Center for Veterinary Medicine.

(FR Doc. 84-14930 Filed 5-31-84; 8:45 am)

BILLING CODE 4160-01-M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 216

[DOD Directive 1322.13]

Identification of Institutions of Higher Learning That Bar Recruiting Personnel From Their Premises

AGENCY: Office of the Secretary, DOD.

ACTION: Final rule.

SUMMARY: This rule updates DOD's implementation of the Act of September 26, 1972, section 606, Pub. L. 92-436, 86

Stat. 734, 740. The statute provides that funds appropriated by the Department of Defense may not be used at any institution of higher learning if military recruiting personnel are being barred by the policy of the institution from the premises of the institution.

EFFECTIVE DATE: This rule was signed by the Deputy Secretary of Defense on May 9, 1984, and will be effective July 2, 1984.

FOR FURTHER INFORMATION CONTACT: Mr. Ronald G. Liveris, Office of the Assistant Secretary of Defense (Manpower, Installations, and Logistics) (Military Personnel and Force Management) (Accession Policy), The Pentagon, Room 2B269, Washington, D.C. 20301, telephone 202-697-9269.

SUPPLEMENTARY INFORMATION: In FR Doc. 82-26699, appearing in the *Federal Register* on September 29, 1982 (47 FR 42757), as amended by FR Doc. 82-31465, appearing in the *Federal Register* on November 17, 1982 (47 FR 31766), the Office of the Secretary of Defense (OSD) published a proposed revision of this part. The Supplementary Information accompanying the proposed revision described the prior history of the rule.

In response to the notice of proposed rulemaking, DOD received six comments. Each comment was reviewed and given careful consideration. The major factors considered in evaluating the public comments are set forth below.

Favorable comments were received with respect to the clarity of the rule and the improved procedures for determining whether an institution should be denied funds under the statutory prohibition. The new procedures are designed to promote a dialogue between the institution and DOD in the event the institution proposes to bar military recruiting on campus. It is DOD's desire to minimize involvement with the placement policies of institutions of higher learning to the extent consistent with the statutory requirements.

Several commenters also noted with approval § 216.3(a), which provides that a bar from recruiting at a subordinate element of an institution which does not effectively bar military recruiting at other subordinate elements of the institution, will be considered only with respect to the elements in which recruiting is effectively barred for the purpose of the prohibition on expenditure of DOD funds. This is not a new policy; rather, it reflects DOD's interpretation of the law and its legislative history as applicable only to the extent that military recruiting is barred by the policy of the institution. Subordinate elements of an institution of higher learning that administer their

own placement policies to permit recruiting will not be subject to a prohibition on receiving DOD funds. It is consistent with DOD's intent to avoid entanglement with the internal decisionmaking processes of institutions of higher learning.

Several comments addressed that portion of § 216.3 that applies the prohibition on expenditure of DOD funds to "circumstances in which a policy of the institution is applied to bar military recruiting personnel because of the policies or practices of the Department of Defense or of a DOD Component." One comment favored this provision; others were opposed. One opponent noted that this might lead to a prohibition on expenditure of funds under the rule with respect to an institution of higher learning that prohibits military recruiting because the institution has a policy of excluding organizations that discriminate against the handicapped. Because the armed forces do not recruit persons with physical handicaps for military service (with certain exceptions), DOD funding for the school would be terminated if the institution barred military recruiters. The opposition to applying the DOD rule, in such circumstances, as expressed in the comments, rested primarily on two general grounds: first, it was contended that the legislative history underlying the statute excludes from the funding cut-off institutions that have recruiting policies generally applicable to all employers; second, applying the funding cut-off in such circumstances would interfere with the constitutional rights of the institutions to academic freedom.

Before discussing the specific details of these comments, several general points are important. First, the Department of Defense does not desire to engage in a confrontation with institutions of higher learning over their career placement policies. The Department has attempted to interpret it in a manner that minimizes friction between the Department and the academic community.

Second, this is not a new interpretation. The issue was raised first in 1980 in an inquiry from an institution of higher learning. The Department replied at that time that it interpreted that law as requiring a funding cut-off when an institution barred military recruiters as a result of military policy even if the institution happened to apply the same recruiting policy to other employers. (In order to ensure that all institutions have adequate notice of this interpretation, the Department will apply it only to actions by institutions