New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803, telephone (617) 273-7113.

SUPPLEMENTARY INFORMATION: This amendment amends Amendment 39-4711 (46 FR 39052), AD 83-17-07, which currently requires a frequent repetitive inspection for cracks in the vertical pylon front spar caps and web on certain Sikorsky Model S-76A helicopters that have attained 2,400 hours' time in service. After issuing AD 83-17-07, the FAA determined that after a specific and optional modification of the vertical pylon has been accomplished, the repetitive inspections specified in the AD are no longer necessary. Therefore, the FAA is amending Amendment 39-4711 by removing the inspection requirement for those helicopters that have incorporated a specific pylon forward and aft spar enforement modification.

Since this amendent provides for incorporation of an optional design feature which would eliminate an existing repetitive inspection requirement, but does not mandate adoption of the modification, it is found that notice and public procedure hereon are unnecessary and the amendment may be made effective in less than 30 days.

The FAA determined that this amendment could involve up to 230 aircraft with an estimated cost of $2,800 for each vertical pylon forward and aft spar modification whenever chosen by an operator. Therefore, I certify that this action (1) is not a "major rule" under Executive Order 12291, and (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). A copy of the final evaluation for this action is contained in the regulatory docket. A copy of it may be obtained by contacting the person identified under the caption **FOR FURTHER INFORMATION CONTACT.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety, Incorporation by reference.

Adoption of the Amendment

§ 39.13 [Amended]

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended by amending Amendment 39-4711 (46 FR 39052), AD 83-17-07, by adding the following new paragraph (f):

* * * * *

(f) For helicopters that have been modified in accordance with Sikorsky's Customer Service Notice No. 76-141B, Part 1, paragraphs A-F(1), or Part 2, paragraphs A-E(1), dated January 15, 1985, vertical stabilizer forward and aft spar reinforcement kits, the inspection requirements in paragraphs (a), (b), and (c) are not applicable.

The manufacturer's specifications and procedures identified and described in this directive are incorporated herein and made a part hereof pursuant to 5 U.S.C. 552(a)(1). All persons affected by this directive who have not already received these documents from the manufacturer may obtain copies upon request to Sikorsky Aircraft, Division of United Technologies, North Main Street, Stratford, Connecticut 06601. These documents also may be examined at the Rules Docket at the Office of the Regional Counsel, Southwest Region, Federal Aviation Administration, 4400 Blue Mound Road, Fort Worth, Texas 76106.

(Secs. 313(a), 601, and 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); 49 U.S.C. 106(g), (Revised, Pub. L. 97-449, January 12, 1983); 14 CFR 11.89)

This amendment becomes effective April 22, 1985.

This amendment amends Amendment 39-4711 (46 FR 39052), AD 83-17-07.

Issued in Fort Worth, Texas, on March 19, 1985.

C.R. Melugin, Jr.,

Director, Southwest Region.

[FR Doc. 85-9240 Filed 4-15-85; 9:22 am]

BILLING CODE 4910-13-M

FEDERAL TRADE COMMISSION

16 CFR Parts 300 and 303

Amendment to Rules and Regulations Under the Wool Products Labeling Act of 1939 and Textile Fiber Products Identification Act

AGENCY: Federal Trade Commission.

ACTION: Notice of final rulemaking.

SUMMARY: Title III of Pub. L. 98-417 amended the Wool Products Labeling Act of 1939 (Wool Act) (15 U.S.C. 68) and the Textile Fiber Products Identification Act (Textile Act) (15 U.S.C. 70) effective December 24, 1984. On November 13, 1984, the Commission published a notice of rulemaking (49 FR 44913) that proposed amendments to the rules and regulations under each Act to reflect the amendments to these Acts. Written comments were invited until December 13, 1984. Approximately seventy-one comments were received and placed on the public record. This notice contains the statement of basis and purpose for the amendments and the text of the rules and regulations as amended.

EFFECTIVE DATE: Title III of Pub. L. 98-417 became effective on December 24, 1984. The amended rules and regulations will become effective on and after May 17, 1985.

ADDRESS: Requests for copies of the amendments to the rules and regulations and the statement of basis and purpose should be sent to Public Reference Branch, Room 130, Federal Trade Commission, 6th and Pennsylvania Ave., NW., Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: Earl Johnson, Federal Trade Commission, 6th and Pennsylvania Ave., NW., Washington, D.C. 20580. Tel: (202) 376-2891.

SUPPLEMENTARY INFORMATION:

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1. Wool Act § 300.3 and Textile Act § 303.16.
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Statement of Basis and Purpose

I. Introduction

The Wool Products Labeling Act of 1939 was enacted by Congress for the expressed purpose of protecting producers, manufacturers, distributors and consumers from the unrevealed presence of substitutes and mixtures in spun, woven, knitted, felted or otherwise manufactured wool products, and for other purposes.[1] Basically, the Act required that each wool product contain a stamp, tag or label showing the fiber content and the name of the manufacturer or the name of someone in the line of distribution of that product.[2]

The Textile Fiber Products Identification Act was enacted by Congress in 1958 with the expressed purpose of protecting producers and consumers against misbranding and false advertising of the fiber content of textile fiber products, and for other purposes.[3] Like the Wool Act, this Act

[1] Pub. L. 850, 76th Cong., 54 Stat. 1128 (1939), 15 U.S.C. 68.

[2] 15 U.S.C. 68b.

[3] Pub. L. 85-897, 72 Stat. 1717 (1958), 15 U.S.C. 70.

basically required each textile product to contain a stamp, tag or label showing the fiber content and the name of the manufacturer or someone in the line of distribution of the product.[4] In addition, the Textile Act required that the label contain the name of the country of origin if the product was imported.[5]

Under each of the Acts the Federal Trade Commission was authorized and directed to issue such rules and regulations as may be necessary for their administration and enforcement.[6] Regulations under the Wool Act were first issued effective July 15, 1941[7] and regulations under the Textile Act were made effective March 3, 1960.[8]

On September 24, 1984, amendments to both Acts were enacted to become effective 90 days thereafter, or on December 24, 1984.[9] The Wool Act was amended to require imported products to be labeled with the country of origin. Both the Textile and Wool Acts were amended to require domestically manufactured products to be labeled with the country of origin. The Senate Committee, in a report on the legislation that became Public Law 98–417, stated that the objective of the legislation was to clarify and improve country of origin labeling requirements for textiles and to increase consumer awareness at the time of purchase.[10]

In addition to the amendments requiring the disclosure of the country of origin, both Acts were amended to require:

(1) The country of origin disclosure to be placed in the neck of garments having necks, or for garments without necks, on a conspicuous spot on the inside or on the outside of the product;

(2) All products to be separately labeled, except hosiery in a retail package;

(3) All packages, in addition to the products, to be labeled unless the packaging is transparent and the individual product label can be seen through the package; and

(4) Mail order catalogs and mail order promotional materials to disclose in the description of each textile and wool product whether the product is made in U.S.A., imported or both.[11]

On November 13, 1984, the Commission published a notice of proposed rulemaking in the **Federal Register**[12] containing alternative procedures for labeling domestic origin and questions relating to the alternatives. The public was asked to comment in writing by December 13, 1984. In response to its request for comment, the Commission received approximately 71 comments and placed these on the public rulemaking record.

II. The Amended Rules

In this section each of the four major aspects of Pub. L. 98–417, i.e., country of origin, location of the label, labeling of packaged products, and country of origin information in printed mail order advertising, is separately discussed. In each subsection, the discussion begins with a description of the statutory changes to the Textile and Wool Acts. The discussion then turns to the proposals and questions raised by the Commission regarding how to implement the changes. Next, the major relevant comments on the issues are discussed. The discussion concludes with an explanation of the regulatory provision adopted by the Commission.

A. Country of Origin

Prior to the passage of Pub. L. 98–417, the disclosure of the country of origin of imported goods was mandated only for goods covered under the Textile Act.[13] For imported goods covered under the Wool Act, the Commission had required the disclosure of foreign origin under Section 5 of the FTC Act.[14] Under Section 5, the Commission also had required disclosure of foreign origin for other imported products such as machinery.[15] Additionally, the Commission had advised importers that a product partially made in a foreign country and partially made in the U.S.A. must have a label disclosing that the product was made in the U.S.A. and that it contained imported components.[16] Prior to the enactment of Pub. L. 98–417 there was no requirement to disclose the country of origin of goods made entirely in the United States, although this information could be voluntarily disclosed.[17]

1. *Origin of Imported Products.* Pub. L. 98–417 amends the Wool Act to require the disclosure of country of origin on labels for imported wool products.[18] As a result, the Wool Act's country of origin disclosure requirement now parallels the requirement under the Textile Act for labeling imported products with the country of origin.[19] The U.S. Customs Service (Customs) of the U.S. Department of Treasury administers two Acts that also require all imported textile and wool products to be labeled with the country of origin.[20] Under those Acts, a single country of origin is used for the purpose of assessing tariffs, enforcing quotas and marking the products. In the past, regulations under the Textile Act have paralleled the regulations issued by Customs.[21]

These final regulations do not change current requirements under the Textile Act for disclosing the country of origin of imported goods.[22] The regulations under the Wool Act for imported wool products have been drafted to implement this statutory amendment to this Act and to parallel the regulations under the Textile Act.[23] Some of the comments on these regulations requested that the Commission adopt a policy statement that the regulatory scheme under the Textile and Wool Acts with respect to country of origin on imported products is intended to be consistent with Customs regulations.[24] Other comments requested that the Commission confirm that the amended rules will not affect the labeling of "807" materials.[25] To the maximum extent consistent with the legislative intent, the Commission intends the final regulations for the disclosure of the country of origin of imported textile and wool products, including those under the 807 program, to be construed in a manner consistent with Customs regulations.[26]

2. *Origin of domestic products.* Pub. L. 98–417 amends both the Textile and Wool Acts to mandate, for the first time, the disclosure of the country of origin for domestic products. The Senate Committee Report on the legislation that eventually became Pub. L. 98–417 states that the amendment adding a requirement for country of origin for

[4] 15 U.S.C. 70b.
[5] Id.
[6] 15 U.S.C. 68d and 15 U.S.C. 70e.
[7] 6 FR 3426 (1941). Also see 16 CFR Part 300.
[8] 24 FR 4460 (1959). Also see 16 CFR Part 303.
[9] Title III, Pub. L. 98–417, 98 Stat. 1585 (1984).
[10] S. Rep. 529, 98th Cong. 2d Sess. (1984).
[11] *Supra.* Note 9.
[12] 49 FR 44913 (1984).
[13] 16 CFR 303.33 (1984).
[14] 16 CFR 300.25(c) (1984). (see note following this section).
[15] See 16 CFR 15.221.
[16] See 16 CFR 15.282 and 15.307 (1984).
[17] See 16 CFR 15.315 and 15.326 (1984).
[18] Supra. Note 9 at section 304.
[19] 15 U.S.C. 70b.
[20] Tariff Act of 1930, 19 U.S.C. 66 and Agriculture Act of 1956, 7 U.S.C. 1854.
[21] Compare 19 CFR Part 134 (1984) and 16 CFR 303.33 (1984).
[22] 16 CFR 303.33 (1984).
[23] See § 300.25a as amended.
[24] FTC Public Record 204–17–1, Comments, Pages 119, 128, 242, 311.
[25] "807" materials are textile or wool products assembled and sewn together in a foreign country of components that came from the United States. The finished products are given special tariff treatment under Item 807.00 of the Tariff Schedules of the United States, 19 U.S.C. 1202.
[26] See 19 CFR Part 134 and 19 CFR 10.22.

domestic products is intended to be consistent with current FTC country of origin labeling requirements.[27]

The Commission's proposed regulations implementing this statutory amendment codified FTC advisory opinions. The proposed regulations required: (1) Items entirely made in the U.S.A. to be labeled with "Made in USA"; (2) items made in the U.S.A. using imported materials to be labeled with that fact, e.g., "Made in U.S.A. of fabric from ————"; and (3) items made partially in a foreign country and partially in the U.S.A. to disclose those facts, e.g., "Assembled and sewn in U.S.A. of components made in ————." The Commission also published an alternative set of proposed regulations and posed several questions concerning these alternatives.[28]

Comments on the proposed regulations and the alternatives that two of the principal sponsors of the Bill submitted, emphasized that the Senate Committee Report language stated that the amendments were intended to be consistent with existing FTC country of origin labeling requirements. The comments also pointed out that advisory opinions issued by the Commission in the past have required products of mixed domestic and foreign origin to specify that the product was made in the United States of imported materials. The comment further stated that the intent of Congress to codify existing Commission precedent in determining appropriate labeling requirements was also articulated in the hearings conducted by the House Committee.[29]

Several other comments proposed that the Commission's regulations adopt the substantial transformation test, which was proposed by the Commission as an alternative regulation and is used by Customs for determining a single country of origin for an imported product.[30] Still other comments favored using the proposed alternative "Principally made in the USA," which was another of the proposed alternatives published for comment.[31] However, other comments noted that such a statement would be vague and uninformative. The comments also noted that a proposed test for determining where the product was principally made, i.e., where more then 50% of the value was added, would be difficult to use.[32]

Comments filed by the American Fiber Textile Apparel Coalition (AFTAC) recommended that the regulations modify existing precedent slightly, by requiring only a statement of origin such as "Made in USA of imported cloth."[33] Several other comments also favored a simplified disclosure, stating that disclosing the identity of the individual countries, in which imported components of American made goods originated, would entail substantial additional costs to maintain and properly dispense large inventories of labels.[34] Similarly, the comment from two of the principal sponsors of the legislation stated the use of "imported" for goods of mixed origin would not be inconsistent with Congressional intent and would preserve the basic goal of the Act. Their comment recommended adoption of the "Made in USA of imported fabric" approach.[35]

Other comments addressed the Commission's discussion regarding how far back in the manufacturing process the Commission would look to determine whether goods made in the United States contain foreign components. In the proposed regulations the Commission stated that it would look at where the cloth or yarn used in the manufacturing process was made.[36] Some comments recommended that this standard be clarified to indicate that each manufacturer would only have to look back *one* step to determine the country of origin, e.g., yarn manufacturers would look to the fiber source, cloth manufacturers to the yarn source, and garment manufacturers to the cloth or yarn source.[37]

Another group of comments addressed the question raised in the proposed regulations, regarding whether items excluded by Section 12 of the Textile Act, such as trim, thread and linings for structural purposes, should be excluded when determining the origin of goods.[38] The comment filed by two of the principal sponsors of this legislation noted that the Senate Report stated that the labeling provisions of the legislation do not apply to goods not covered by the Textile Act. The comment then stated that given this language, these excluded items should not be included in origin determinations.[39] The same treatment applies to items excluded under a similar exemption provision in the Wool Act.[40]

Comments were also received from the United States Customs Service concerning products partially made in a foreign country and partially made in the United States. Customs commented that its regulations may be interpreted to require that the largest component or part of an unfinished product entering the United States be marked with the foreign country of origin in cases which Customs determines that substantial transformation had taken place abroad.[41] Customs noted that its required label might conflict with the Commission's proposed label requirements, i.e., Customs' label with a single country of origin based on substantial transformation compared to an FTC required label disclosing the foreign and domestic aspects of disclosure.

After considering the comments, the statute, and the legislative history and intent, the Commission has decided to adopt final regulations under the Textile Act and Wool Act that provide for three different categories of domestic origin disclosures.[42] First, for products made entirely in the United States, the regulation provides that the words "Made in USA" or some other clear and equivalent term must be used. Thus, terms such as "Product of USA", "Crafted with pride in USA", "Tailored in USA", "Manufactured in USA," "Made in New York, USA" and other equivalent markings are acceptable.[43]

Second, for products made in the United States using foreign materials, the regulation requires a disclosure that the product was, for example, "Made in USA of imported fabric," or equivalent terms. Finally, for products partially manufactured in the United States and partially manufactured in a foreign country, the regulation requires a disclosure that the product was, for example, "Sewn in USA of imported components" or a similar disclosure.

For all the categories, the Commission is only requiring that the manufacturer go back one manufacturing step to determine origin. Thus, a manufacturer of yarn would look back to the source of its fiber. A manufacturer of cloth would look back to the source of its yarn and the garment manufacturer would look back to the source of the yarn in garments that are knitted or to the

[27] Supra, Note 10 at section 2.
[28] Supra, Note 12 at page 44917.
[29] Supra, Note 24 at page 54.
[30] Supra, Note 24 at pages 34, 37, 41, 47, 85, 193, 207, 219, 305.
[31] Supra, Note 24 at pages 128, 170, 262, 274, 276.
[32] Supra, Note 24 at pages 119, 272, 296, 303.
[33] Supra, Note 24 at page 311.
[34] Supra, Note 24 at pages 18, 34, 193, 242.
[35] Supra, Note 24 at page 54.
[36] Supra, Note 12, page 44914.
[37] Supra, Note 24 at pages 242, 311, 318.
[38] Supra, Note 12 at question 3.
[39] Supra, Note 24 at page 54.
[40] 15 U.S.C. 68b (d).
[41] Supra, Note 24 at page 189.
[42] See Amendments § 300.25a and § 303.33.
[43] See Amendments § 300.25a(a)(2) and § 303.33(a)(2).

source of the cloth. Additionally, in determining origin, materials that are otherwise excluded under the Acts do not have to be considered.

For the last two categories of products (i.e., those having both domestic and imported components or aspects of manufacturer to be disclosed), the regulations permit the foreign components or manufacturing operation to be disclosed by using the general term imported or similar terms rather than specifying the foreign country or countries involved.

Similarly, in the last two categories, if the country of origin disclosure required by the Customs Service appears in the neck of the product, that disclosure would also satisfy the Commission's requirement that the country of origin be disclosed in the neck of the product.

B. Location of the Label

The Textile and Wool Acts, as amended by Pub. L. 98–417, now state that the required label must be located in the inside neck of a garment that has a neck, midway between the shoulder seams.[44] According to the legislative history, the purpose of this requirement is to standardize the location of this information.[45] Other provisions of the existing regulations state that all information required to be disclosed by the Act must be disclosed in one place.[46] The Commission proposed an amended regulation under each Act that mandated location of the label in the neck of garments with a neck midway between the shoulder seams. Under the proposed regulation labels for other garments would be located in a conspicuous spot on the inside or outside of the garment.[47]

Many comments noted that the center of the back of the neck was the common location for the brand label and that displacement of the brand label could cause a serious hardship on established sales practices.[48] They suggested that the origin label be allowed to be located adjacent to the brand label. Other comments stated that requiring all the information to be placed in the neck also could cause that area to be crowded or be unsightly.[49] The comments suggested permitting the information to be separated, i.e., allowing the country of origin to be disclosed in the neck alone as long as the other required information, e.g., fiber content and name of the company or RN, was located elsewhere on the garment.

Comments submitted by two of the principal sponsors of the legislation indicated the underlying goal of the location requirement was to standardize the location of the country of origin disclosure so that consumers could find the information quickly and easily. The comment further stated that to the extent the location requirement would displace other label information, the legislation's goal would be satisfied if the origin label was placed immediately next to the other label, as long as it was conspicuous to the consumer.[50]

On the basis of the information provided by all the comments, the Commission has added two provisos to the final regulations requiring the country of origin information to be disclosed on a label on the inside center of the neck. The first proviso permits the required disclosures of origin, fiber content, and name of the manufacturer or RN to be placed in close proximity to a label such as a brand label already affixed to the inside center of the neck, providing the required lable remains conspicuous to the consumer. This means that the required label should not be placed so far from the center of the neck that it can not be seen as readily as the label in the center neck position. This approach is also consistent with the Customs Service requirement that origin information be placed in the immediate area of the neck.

A second proviso allows the manufacturer to put all the required information, i.e., origin, fiber content, name or RN of the manufacturer, on a hang tag or a label attached to a conspicuous place on the inside or outside of the garment, provided a label with country of origin appears on the inside neck either in the center or just adjacent to the center label. Thus, the Congressional purpose of providing a standard location for the country of origin is preserved, the crowding of other information in the neck area is alleviated, and the pre-existing requirement that all required information appear on the label together, is retained.[51]

C. Labeling Packaged Products

Prior to the amendments, the Textile Act provided that a label was not required on products in a package if (1) the products were intended for sale to the ultimate consumer in such package, (2) the package had a label containing the required information regarding the products and (3) the information on the label was equally applicable to each product in the package.[52] Pub. L. 98–417 alters this provision to make it only applicable to hosiery products, but extends the exemption to hosiery under the Wool Act as well as the Textile Act.

The Commission's proposed regulations implemented the amended statute by requiring that all products covered by the Textile and Wool Acts, except hosiery in a package as described above, bear the required label.[53] Further, as the amended Acts provide, the proposed regulations required any package of textile or wool products intended for sale to the ultimate consumer to be labeled with the required information unless the information pertaining to the products can be clearly seen through the packaging.[54]

Two comments stated that the term "package" as used in the proposed rules could be mistakenly interpreted to include shipping packages and the dust covers that are used to protect hanging garments until they are put on display by the retailer.[55] Another comment stated that table linens were commonly packaged with all information on the package or on a label that was slipped inside transparent packaging. The comment suggested that an exemption be granted from attaching a label to the product for this type of packaging.[56]

The Commission's final amended regulations emphasize that the type of package that is required to be labeled is one which is intended to remain unbroken and intact until sale to the ultimate consumer.[57] Thus, packaging or wrapping used only for shipping or delivering packages to consumers or packaging that is used as a protective cover until the product is put on display for retail sale is not the type required to be labeled. As to the suggestion that exemptions be granted for other types of packaging, the Commission notes that the Senate Committee report states that the Committee intended the exception to individual product labeling to apply only to hosiery.[58]

D. Origin in Mail Order Catalogs and Promotional Materials

Pub. L. 98–417 amended both the Textile and Wool Acts to mandate that

[44] Supra, Note 9 at section 303 and section 305.
[45] Supra, Note 10 at Section 4.
[46] See 16 CFR 300.10 and 303.16 (1985).
[47] 49 FR 44913, 44916, 44918 (1984).
[48] Supra, Note 24 at pages 20, 80, 82, 133.
[49] Supra, Note 24 at pages 45, 47, 85, 119, 128, 182, 193, 237, 311.
[50] Supra, Note 24 at page 54.
[51] See Amendments at § 300.5(b) and § 303.15(b).
[52] 15 U.S.C. 70b (e).
[53] Supra, Note 9 at section 302 and section 306.
[54] Id.
[55] Supra, Note 24 at pages 219, 266.
[56] Supra, Note 24 at pages 186.
[57] See Amendments § 300.15 and § 303.28.
[58] Supra, Note 10 at Section 3.

each description of a textile or wool product contained in a mail order catalog or in mail order promotional material must contain a clear and conspicuous statement that such product is processed or manufactured in the United States of America, or imported or both.[59]

In addition to implementing this requirement, the Commission's proposed regulations included a definition of "mail order catalog" and "mail order promotional material."[60] The proposed regulations also permitted other words or phrases with the same meaning to be used in place of made in USA, imported or both.[61] Further, the Commission posed two questions concerning this requirement. First, whether the disclosure "Made in USA and imported" should be allowed for goods made in USA with imported materials, and for goods partially made in a foreign country and partially made in the U.S.A.[62] Second, whether general disclaimers should be permitted as alternatives to putting a disclosure in the description of each product.[63]

In response to the first question, a number of comments favored the use of "Made in USA and Imported" for goods made in the U.S.A. out of imported materials, and for goods partially made in the U.S.A. and partially made in a foreign country.[64] Comments from two of the principal sponsors of the legislation noted that using the term "Made in USA and Imported" to convey mixed origin may be confusing to consumers. The comment suggested that the Commission consider requiring a legend in each catalog to explain the meaning of the origin terms until consumers became familiar with their meanings.[65]

In response to the second question, a number of comments supported the use of general disclaimers.[66] Two comments, however, stated that the only way to transmit effectively the origin information of each product was to put it in each description.[67] The comment of the two principal sponsors of the legislation noted that the statutory language expressly requires the origin disclosure to be in each product description that the legislative history supporting this requirement is very clear.[68]

Finally, two comments suggested clarifying the definitons of "mail order catalog" and "mail order promotional material" to make clear that a general advertisement does not fall within the Act simply because some consumer may make purchases by telephone from the store placing the advertisement.[69]

The Commission's final regulations containing definitions of the terms "mail order catalog" and "mail order promotional material" have been clarified to indicate that the statute and regulations cover advertising that solicits the retail buyer to purchase a product by telephone, mail or some other similar method without first examining that product.[70] The requirement to disclose the origin of the product does not apply to regular advertising that is used solely to attract the retail buyer to the store to purchase the product. Additionally, the definitions now make clear that the requirement to disclose origin information in mail order advertising applies only to printed advertising that is going to retail consumers. The requirement does not apply to advertising by manufacturers or wholesalers that is meant only for retailers.

The final regulations also implement the statutory requirement that each description contain a clear and conspicuous statement that the product was made in the U.S.A., imported or both.[71] Although general disclosures of the origin of all products in the mail order catalog or any part thereof are permissible, such general statements or disclaimers do not satisfy the requirements of the Act or the regulations. The regulations also provide that words or phrases other than "Made in USA" or "Imported" may be used provided they have the same meaning. Further, the regulations also indicate that the origin statement used in mail order materials must be consistent with the origin labeling on the product being advertised. For example, a product labeled "Made in USA of imported fabric" could be advertised as "Made in USA and imported," "Made in USA of imported fabric", Made in USA of (X Country) fabric" or by other words of similar meaning; but "Made in USA" alone would be inconsistent and therefore prohibited.

Because the required disclosures in each product description are extremely short and not necessarily self-explanatory, it is important that the permitted terms be used in a clear and consistent manner. For example, "Made in USA and Imported" should be used to indicate partial manufacture in USA and partial manufacture in a foreign country, while "Made in USA or Imported" should be used to reflect that a product was being obtained both from a domestic source and a foreign source. To assist consumers, particularly at the outset, the Commission strongly encourages mail order advertisers to include a legend in their advertising explaining the meaning of their country of origin disclosures.

E. Other Rule Changes

A few minor changes to other regulations under both the Wool and Textile Acts were necessary to ensure all regulations correspond with the requirements of the amendments to these Acts. These minor changes are briefly explained below.

1. *Wool Act § 300.3 and Textile Act § 303.16.* Each of these sections lists the required information that must appear on the label, e.g., fiber content, name or RN of the manufacturer, and in the case of the Textile Act, origin of imported products. In addition to the information previously required, the final regulations now list the origin of domestic products, for the Textile Act, and origin of imported and domestic products under the Wool Act as required information.

2. *Wool Act § 300.5 and Textile Act § 303.15.* Subsection (a) of each of these regulations now makes it clear that every product, whether packaged or unpackaged, must have a label bearing the required information. The exemption for hosiery under certain packaging conditions is contained in subsection (c) of each rule.

3. *Wool Act § 300.10.* This rule contains an example of the information the Act requires to be disclosed. Until now, the Wool Act did not require disclosure of the country of origin. Therefore, the country of origin disclosure has been added to the example in this rule.

III. Regulatory Flexibility Act

In publishing the proposed amendments, the Commission determined that the provisions of the Regulatory Flexibility Act[72] requiring an initial regulatory analysis were not applicable to the amendments because the regulations do not appear to have a significant economic impact on a substantial number of small entities.[73]

[59] Supra, Note 9 at section 303 and section 305.
[60] Supra, Note 12 at page 44916 and 44918.
[61] Supra, Note 12 at page 44917 and 44918.
[62] Supra, Note 12 at page 44916.
[63] Id.
[64] Supra, Note 24 at pages 170, 266, 318.
[65] Supra, Note 24, at page 54.
[66] Supra, Note 24 at pages 60, 61, 133, 170, 193, 219, 266, 272, 280, 296, 324.
[67] Supra, Note 24 at pages 119, 318.
[68] Supra, Note 24 at pages 54, 346.
[69] Supra, Note 24 at pages 191, 193.
[70] See amendments § 300.1 and § 303.1.
[71] See amendments § 300.25b and § 303.34.
[72] 5 U.S.C. 603, 604.
[73] Supra, Note 12 at Section C.

The Commission noted that the economic costs are primarily statutorily imposed and the Commission's amendments impose few, if any, independent additional costs. In light of the above, it was certified under the provisions of section 3 of the Regulatory Flexibility Act[74] that the proposed regulations would not have a significant economic impact on a substantial number of small entities.

The Commission requested comments on the effects of these amendments and asked for numerical estimates if the amendments were believed to affect costs, profitability, competitiveness, or employment in small entities. The comments, however, appear to address the compliance obligations that have been statutorily, rather than administratively, imposed, noting generally that compliance could be burdensome. On the basis of all the information before it, the Commission has determined the final regulations will not have a significant economic impact on a substantial number of small entities. Consequently, the Commission concludes that a final regulatory flexibility analysis is not required and has filed a certificate with the Small Business Administration to that effect.

IV. Paperwork Reduction Act

In the publication of the proposed amendments, the Commission noted that the amended rules contain provisions that constitute information collection requirements under the Paperwork Reduction Act.[75] Consequently, a supplement to existing clearances was submitted to the Office of Management and Budget.[76] The supplement was approved by OMB on Decemeber 4, 1984.[77]

V. Effective Date

Title III of Pub. L. 98–417 amending the Textile and Wool Labeling Acts became effective on December 24, 1984. Therefore, all textile and wool products covered by these Acts that enter production on or after December 24, 1984 must be labeled in accordance with the amended Acts. All mail order catalogs and mail order promotional materials that are prepared and sent to the printer on or after December 24, 1984 must contain the origin information as required by the amended Acts.

[74] 5 U.S.C. 605(b).

[75] Supra, Note 12 at Section D.

[76] See OMB Clearances Nos. 3084–0052 and 3084–0053.

[77] Notice of Correction Made By OMB to Carl Hevener, Federal Trade Commission, dated Dec. 4, 1984.

These amended regulations become effective on May 17, 1985. They apply to all textile and wool products covered by the Acts that enter production on or after that date and all mail order catalogs and mail order promotional material prepared and sent to the printer on or after that date.

List of Subjects

16 CFR Part 300

Labeling, Textile, Trade practices, Warranties, Wool.

16 CFR Part 303

Labeling, Textile, Trade practices.

Accordingly, it is proposed that Chapter I of 16 CFR Part 300 be amended as follows:

Authority: 15 U.S.C. 68 *et seq.* and 15 U.S.C. 70 *et seq.*

PART 300—RULES AND REGULATIONS UNDER THE WOOL ACT

1. In § 300.1, paragraphs (g), (h) and (i) are added as follows:

§ 300.1 Terms defined.

* * * * *

(g) The term *United States* means the several States, the District of Columbia, and the territories and possessions of the United States.

(h) The terms "mail order catalog" and "mail order promotional material" mean any printed materials used in the direct sale or direct offering for sale of wool products that are distributed or shown to ultimate consumers and solicit the ultimate consumers to purchase such wool products by mail, telephone or some other method without examining the actual product purchased.

(i) The terms label, labels, labeled, and labeling mean the stamp, tag, label, or other means of identification, or authorized substitute therefore, required to be on or affixed to wool products by the Act or Regulations and on which the information required is to appear.

2. In § 300.3 add paragraph (a)(4) as follows:

§ 300.3 Required label information.

(a) * * *

(4) The name of the country where the wool product was processed or manufactured.

* * * * *

3. Section 300.5 is revised to read as follows:

§ 300.5 Required label and method of affixing.

(a) A label is required to be affixed to each wool product and, where required, to its package or container in a secure manner. Such label shall be conspicuous and shall be of such durability as to remain attached to the product and its package throughout any distribution, sale, resale and until sold and delivered to the ultimate consumer.

(b) Each wool product with a neck must have the label affixed to the inside center of the neck midway between the shoulder seams *provided*, however, that the required label may appear in close proximity to another label affixed to the inside center of the neck as long as the required label remains conspicuous to the consumer and, *provided further*, that if the country of origin is disclosed on a label affixed to the inside center of the neck or in close proximity, the label containing the country of origin, fiber content and RN or name of the company may appear in another conspicuous location on the inside or on the outside of the garment. All other wool products shall have the label affixed to a conspicuous spot on the inner side of the product or in a conspocuous place on the outside of the product.

(c) In the case of hosiery products, this section does not require affixing a label to each hosiery product contained in a package if, (1) such hosiery products are intended for sale to the ultimate consumer in such package, (2) such package has affixed to it a label bearing the required information for the hosiery products contained in the package, and (3) the information on the label affixed to the package is equally applicable to each wool product contained therein.

4. In § 300.10 paragraph (a) is revised to read as follows:

§ 300.10 Arrangement of label information.

(a) All items or parts of the information required to be shown and displayed in the label of the product, shall be set forth consecutively and separately on the outer surface of the label, in immediate conjunction with each other, and in type or lettering plainly legible and conspicuous, and all parts of the required fiber content information shall appear in type or lettering of equal size and conspicuousness; such as for example:

Distributed by:
John Q. Doe Co., Inc.,
New York, N.Y.

Made of
60% WOOL
40% RECYCLED WOOL
EXCLUSIVE OF ORNAMENTATION

Made in U.S.A.

provided, however, that the required name or registered identification number may appear on the reverse side

of the label if it is plainly legible, conspicuous and accessible. On products as to which sectional disclosure is used, an additional non-deceptive label may be used showing the complete fiber content information with percentages as to a particular section or area of the product and specifying the section or area referred to.

* * * * *

5. Section 300.15 is revised to read as follows:

§ 300.15 Labeling of containers or packaging of wool products.

When wool products are marketed and delivered in a package which is intended to remain unbroken and intact until after delivery to the ultimate consumer, each wool product in the package, except hosiery, and the package shall be labeled with the required information. If the package is transparent to the extent it allows for a clear reading of the required information on the wool product, the package is not required to be labeled.

§ 300.25 [Amended]

6. Section 300.25 is amended by removing the last four words in the title and removing paragraph (c) and the note that follows.

7. Section 300.25a is added as follows:

§ 300.25a Country where wool products are processed or manufactured.

(a) In addition to the other information required by the Act and Regulations:

(1) Each imported wool product shall be labeled with the name of the country where such imported product was processed or manufactured;

(2) Each wool product completely made in the United States of materials that were made in the United States shall be labeled using the term "Made in U.S.A." or some other clear and equivalent term.

(3) Each wool product made in the United States, either in whole or part, of imported materials shall contain a label disclosing these facts; for example:

"Made in USA of imported fabric"

or

"Knitted in USA of imported yarn" and

(4) Each wool product partially manufactured in a foreign country and partially manufactured in the United States shall contain on the label the following information:

(i) The manufacturing process in the foreign country and in the USA; for example:

"Imported cloth, finished in USA",

or

"Sewn in USA of imported components

or

"Made in (foreign country), finished in USA"

(ii) When the U.S. Customs Service requires an origin label on the unfinished product, the manufacturing processes as required in paragraph (a)(4)(i) of this section or the name of the foreign country required by Customs, for example:

"Made in (foreign country)"

(b) For the purpose of determining whether a product should be marked under paragraphs (a) (2), (3), or (4) of this section, a manufacturer needs to consider the origin of only those materials that are covered under the Act and that are one step removed from that manufacturing process. For example, a yarn manufacturer must identify fiber if it is imported, a cloth manufacturer must identify imported yarn and a household product manufacturer must identify imported cloth or imported yarn for household products made directly from yarn, or imported fiber used as filling for warmth.

(c) The term country means the political entity known as a nation. Except for the United States, colonies, possessions or protectorates outside the boundaries of the mother country shall be considered separate countries, and the name thereof shall be deemed acceptable in designating the country where the wool product was processed or manufactured unless the Commission shall otherwise direct.

(d) The country where the imported wool product was principally made shall be considered to be the country where such wool product was processed or manufactured. Further work or material added to the wool product in another country must effect a basic change in form in order to render such other country the place where such wool product was processed or manufactured.

(e) The English name of the country where the imported wool product was processed or manufactured shall be used. The adjectival form of the name of the country will be accepted as the name of the country where the wool product was processed or manufactured, provided the adjectival form of the name does not appear with such other words so as to refer to a kind of species of product. Variant spellings which clearly indicate the English name of the country, such as Brasil for Brazil and Italie for Italy, are acceptable. Abbreviations which unmistakenly indicate the name of a country, such as *Gt. Britain* for *Great Britain*, are acceptable.

(f) Nothing in this Rule shall be construed as limiting in any way the information required to be disclosed on labels under the provisions of any Tariff Act of the United States or regulations prescribed by the Secretary of the Treasury.

8. Section 300.25b is added as follows:

§ 300.25b Country of origin in mail order advertising.

When a wool product is advertised in any mail order catalog or mail order promotional material, the description of such product shall contain a clear and conspicuous statement that the product was either made in U.S.A., imported, or both. Other words or phrases with the same meaning may be used. The statement of origin required by this section shall not be inconsistent with the origin labeling of the product being advertised.

PART 303—RULES AND REGULATIONS UNDER THE TEXTILE ACT

1. In § 303.1, paragraph (u) is added as follows:

§ 303.1 Terms defined.

* * * * *

(u) The terms "mail order catalog" and "mail order promotional material" mean any printed materials used in the direct sale or direct offering for sale of textile products that are distributed or shown to ultimate consumers and solicit the ultimate consumers to purchase such textile products by mail, telephone or some other method without examining the actual product purchased.

2. Section 303.15 is revised to read as follows:

§ 303.15 Required label and method of affixing.

(a) A label is required to be affixed to each textile product and, where required, to its package or container in a secure manner. Such label shall be conspicuous and shall be of such durability as to remain attached to the product and its package throughout any distribution, sale, resale and until sold and delivered to the ultimate consumer.

(b) Each textile fiber product with a neck must have the label affixed to the inside center of the neck midway between the shoulder seams *provided*, however, that the required label may appear in close proximity to another label affixed to the inside center of the neck as long as the required label remains conspicuous to the consumer and, *provided further*, that if the country of origin is disclosed on a label affixed to the inside center of the neck or in close proximity, the label containing the country of origin, fiber content, and RN

or name of the company may appear in another conspicuous location on the inside or on the outside of the garment. All other textile products shall have the label affixed to a conspicuous spot on the inner side of the product or in a conspicuous place on the outside of the product.

(c) In the case of hosiery products, this section shall not be construed as requiring the affixing of a label to each hosiery product contained in a package if, (1) such hosiery products are intended for sale to the ultimate consumer in such package, (2) such package has affixed to it a label bearing the required information for the hosiery products contained in the package, and (3) the information on the label affixed to the package is equally applicable to each textile fiber product contained therein.

3. In § 303.16, paragraph (a)(3) is revised to read as follows:

§ 303.16 Arrangement and disclosure of information on labels.

(a) * * *

(3) The name of the country where such product was processed or manufactured as provided for in Rule 33.

* * * * *

4. Section 303.28 is revised to read as follows:

§ 303.28 Products contained in packages.

When textile products are marketed and delivered in a package which is intended to remain unbroken and intact until after delivery to the utlimate consumer, each textile product in the package, except hosiery, and the package shall be labeled with the required information. If the package is transparent to the extent it allows for a clear reading of the required information on the textile product, the package is not required to be labeled.

5. In § 303.33, paragraph (a) is revised, paragraphs (b) through (e) are redesignated (c) through (f), a new paragraph (b) is added, and newly redesignated paragraph (c) is revised to read as follows:

§ 303.33 Country where textile fiber products are processed or manufactured.

(a) In addition to the other information required by the Act and Regulations:

(1) Each imported textile fiber product shall be labeled with the name of the country where such imported product was processed or manufactured;

(2) Each textile fiber product completely made in the United States of materials that were made in the United States shall be labeled using the term "Made in U.S.A." or some other clear and equivalent term.

(3) Each textile fiber product made in the United States, either in whole or part, of imported materials shall contain a label disclosing these facts; for example:

"Made in USA of imported fabric"

or

"Knitted in USA of imported yarn" and

(4) Each textile product partially manufactured in a foreign country and partially manufactured in the United States shall contain on the label the following information:

(i) The manufacturing process in the foreign country and in the USA; for example:

"Imported cloth, finished in USA",

or

"Sewn in USA of imported components",

or

"Made in (foreign country), finished in USA"

(ii) When the U.S. Customs Service requires an origin label on the unfinished product, the manufacturing processes as required in paragraph (a)(4)(i) of this section or the name of the foreign country required by Customs, for example:

"Made in (foreign country)"

(b) For the purpose of determining whether a product should be marked under paragraphs (a) (2), (3), or (4) of this section, a manufacturer needs to consider the origin of only those materials that are covered under the Act and that are one step removed from that manufacturing process. For example, a yarn manufacturer must identify fiber if it is imported, a cloth manufacturer must identify imported yarn and a household product manufacturer must identify imported cloth or imported yarn for household products made directly from yarn, or imported fiber used as filling for warmth.

(c) The term country means the political entity known as a nation. Except for the United States, colonies, possessions or protectorates outside the boundaries of the mother country shall be considered separate countries, and the name thereof shall be deemed acceptable in designating the country where the textile fiber product was processed or manufactured unless the Commission shall otherwise direct.

* * * * *

6. Section 303.34 is revised to read as follows:

§ 303.34 Country of origin in mail order advertising.

When a textile fiber product is advertised in any mail order catalog or mail order promotional material, the description of such product shall contain a clear and conspicuous statement that the product was either made in U.S.A., imported, or both. Other words or phrases with the same meaning may be used. The statement of origin required by this section shall not be inconsistent with the origin labeling of the product being advertised.

Dated: April 12, 1985.

By direction of the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 85-9262 Filed 4-15-85; 10:46 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 444 and 448

[Docket No. 80N-0012; DESI Nos. 8924 and 10826]

Oligosaccharide and Peptide Antibiotic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations by (1) revising monographs to provide public standards for two combination antiinfective dermatological products by increasing the minimal levels of bacitracin and polymyxin B, deleting neomycin sulfate, and providing for over-the-counter use, and (2) adding new monographs to provide public standards for two additional combination dermatological products that heretofore have been released pending a final determination of effectiveness. The products were subject to the Drug Efficacy Study Implementation (DESI) program; reformulations covered by these public standards have been found to be effective.

DATES: Effective April 17, 1985; comments, notice of participation, and requests for hearing by May 17, 1985; data, information, and analyses to justify a hearing by June 17, 1985.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joan Eckert, Center for Drugs and Biologics (HFN-815), Food and Drug