9. Section 600.115 is amended by revising paragraph (c)(2) to read as follows:

§ 600.115 Performance reports.

* * * * *

(c) * * *

(2) Annual performance reports shall be submitted within 90 days after the end of the 12-month period (generally the budget period) covered by the report or with, or as part of, any continuation or renewal application if so specified in either any pertinent program rules or the terms and conditions of award.

* * * * *

10. Section 600.119 is amended by revising paragraphs (c)(1) (i) and (ii) and adding a new paragraph (c)(1)(iii) to read as follows:

§ 600.119 Procurement under grants and subgrants.

* * * * *

(c) * * *

(1) * * *

(i) Except as provided in paragraph (c)(1)(iii) of this section, the value of the contract is expected to exceed $5,000 in the aggregate and the grantee or subgrantee is not a State government, local government, or Indian tribal government.

(ii) Except as provided in paragraph (c)(1)(iii) of this section, the value of the contract is expected to exceed $10,000 in the aggregate, and the grantee or subgrantee is a State government, local government, or Indian tribal government.

(iii) In the case of a research grant, the value of the contract is expected to exceed $25,000 in the aggregate, regardless of the grantee's or subgrantee's organizational type.

* * * * *

[FR Doc. 86-24365 Filed 10-27-86; 8:45 am]

BILLING CODE 6450-01-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 175

[T.D. 86-194]

Tariff Classification of Prefinished Hardboard Siding

AGENCY: Customs Service, Treasury.

ACTION: Final interpretive rule.

SUMMARY: Customs has reached a decision regarding the tariff classification of certain imported prefinished hardboard lap siding. The current tariff classification was challenged administratively by the filing of a domestic interested party petition. That petition was denied by Customs. In the subsequent court proceeding contesting the denial by Customs, an alternative classification not previously considered was suggested. Customs was directed by the court to consider the alternative classification. Accordingly, Customs published a notice requesting public comments on the alternative classification. This document advises the public that the alternative classification has been adopted.

DATES: This decision will be effective with respect to merchandise entered, or withdrawn from warehouse, for consumption after 30 days from the date of publication in the Customs Bulletin.

FOR FURTHER INFORMATION CONTACT: Jeremy N. Baskin, Classification and Value Division, (202-566-8181).

SUPPLEMENTARY INFORMATION:

Background

Customs has reviewed its position regarding the tariff classification of certain imported prefinished hardboard lap siding. The product in question is a plank of hardboard, 7/16-inch thick, and either 9 or 12 inches wide. Approximately 1 inch from the bottom, a hard plastic locking strip or "spline" is fixed into a groove in the back of each plank. The top edge of each plank is machined to form a groove or "rabbet", which fits the spline in the plank above. The planks are prefinished at the time of importation. Part of the manufacturing process involves the application of a newsprint paper face to the wet wood fiber mat, which mat has a water content of 70 percent. This occurs prior to compression and heat treatment which forms the hardboard planks, and prior to the sawing and finishing operations which form the prefinished siding. Acrylic latex paint is also applied to the planks prior to importation. The current tariff classification is under the tariff provision for "Other boards, of vegetable fibers (including wood fibers) . . .", in item 245.90, Tariff Schedules of the United States (TSUS) (19 U.S.C. 1202), a duty-free provision.

Customs published a notice in the **Federal Register** on March 22, 1982 (47 FR 12258), acknowledging receipt of a petition from a domestic interested party filed under § 516, Tariff Act of 1930, as amended (19 U.S.C. 1516). The notice solicited public comments on the merits of the petition. The deadline for receipt of comments was subsequently extended by a **Federal Register** notice published on May 27, 1982 (47 FR 23249). The petitioner claimed that the proper classification of the siding should be under the tariff provision for other hardboard in item 245.30, TSUS. The current duty rate under item 245.30, TSUS, is 7.5 percent ad valorem.

In accord with the administration practice concerning the disposition of domestic interested party petitions as set forth in Part 175, Customs Regulations (19 CFR Part 175), by a ruling dated October 29, 1982, Customs informed the petitioner that the comments received in response to the notice had been considered and, upon review of the matter, it was decided to deny the petition and to continue to classify the imported siding in item 245.90, TSUS.

In response to the October 29, 1982, ruling, by letter of November 29, 1982, the petitioner filed notice of its intention to contest the decision in accordance with § 516(c), Tariff Act of 1930, as amended (19 U.S.C. 1515(c)), and § 175.23, Customs Regulations (19 CFR 175.23).

By publication of T.D. 83-104 in the **Federal Register** on May 11, 1983 (48 FR 21231), Customs informed the public of the petitioner's desire to contest the decision, and gave a detailed account of the proceedings to that date together with a full explanation of the reasons for denying the petition.

In the subsequent proceeding contesting the classification before the Court of International Trade, *American Hardboard Association v. United States and MacMillan Bloedel, Ltd.*, Party-in-Interest, Court No. 83-9-01301, a tariff classification not previously considered was suggested. On January 27, 1986, the Court remanded the case to Customs for a decision on the correctness of the current tariff classification as opposed to the newly suggested alternative classification under the provision for "Building boards . . . Laminated boards . . .", in item 245.80, TSUS. Materials classified under item 245.80, TSUS, are currently subject to a compound rate of duty of 1.4 cents per pound, plus 2.6 percent ad valorem.

Accordingly, in order to properly consider the issue, by notice published in the **Federal Register** of March 11, 1986 (51 FR 8338), Customs requested comments on classification of the siding in item 245.80, TSUS, as opposed to classification in item 245.90, TSUS. The merchandise was more fully described in a supplemental document published in the **Federal Register** of April 15, 1986 (51 FR 12712). The six comments received in response to these notices have been fully analyzed and are discussed below.

Analysis of Comments

Four comments supported the continued classification of the siding under item 245.90, TSUS. The remaining comments advocated the alternative classification of the product as laminated building boards under item 245.80, TSUS.

One commenter stated that the subject board is face finished rather than laminated. Headnote 2, Schedule 2, Part 3, TSUS, defines the term "face finished" as including boards that have been overlaid with paper. Because of this definition the commenter claims that the board cannot be considered laminated. Customs does not agree. Face finishing and lamination are unrelated concepts. The superior heading for both items 245.80 and 245.90, TSUS, which reads "Building boards, . . . , whether or not face finished", suggests that classification under those items is not based on face finishing. A face finished board is not precluded from classification as a laminated board.

One commenter cites the lexicographical definition of "laminate" and suggests that the subject merchandise cannot be included. The commenter notes that the noun "laminate" is defined as a product "composed of layers of firmly united material", or "consisting of laminae." "Lamina", the singular form of "laminae", is defined as a "thin plate or scale." The verb "laminate" is defined as "to make by uniting superimposed layers of one or more materials (as by means of adhesives or bolts)." The commenter concludes that the common meaning of the terms "laminate" or "laminated" does not cover the subject product because: (1) It does not consist of laminae because there are no thin plates or scales; (2) it is not made by uniting superimposed layers by means of adhesives or bolts; and (3) it is not composed of layers of firmly united material because there are not visible layers in the merchandise as a finished article.

Customs does not agree. No reasoning is provided to suggest why the newspaper applied to the wet mat layer during manufacture cannot be considered to be a thin plate. Synthetic resins which aid in the bonding process are added to the wet mat before heat and pressure are applied. Thus, the product is made by uniting the superimposed newsprint layer to the wet mat by means of an adhesive. There is nothing in the lexicographical definition cited that requires visible layers to be in evidence in a laminated building board.

Another commenter cites a lexicographical definition which claims the term laminated describes products that are "made by bonding or impregnating superimposed layers (as of paper, wood or fabric) with resin and compressing under heat." This common definition supports classification under item 245.80, TSUS, which covers laminated boards bonded in whole or in part with synthetic resins.

One commenter suggests that the commercial meaning of the term "laminated board" would not include the subject hardboard lap siding. He cites the U.S. Department of Commerce publication *Commercial Standard CS 251–63: Hardboard,* effective February 11, 1963, which describes laminated hardboard as follows:

> Hardboard laminated with an adhesive in multiple plies to obtain greater thickness. These products are used for special purposes where added thickness or two smooth surfaces are desired. Laminated hardboards are available for internal or external use.

The commenter concludes that in order to be a laminated hardboard, a product must have multiple plies of finished boards of the same material (such as wood), bonded together with an adhesive (such as glue). The commenter states that the boards are required to be in layers, and they must be in a finished form when bonded.

The commenter draws conclusions that are not evident from the commercial definition cited. The subject board is laminated with the newsprint layer to obtain a smoother surface that can be more easily finished. The commercial definition does not limit the product to include only finished boards of the same material bound together with an adhesive. Customs believes that the commercial definition of laminated hardboard includes the subject product.

One commenter notes that advertising literature published by the manufacturer of the subject board claims it to be manufactured by a process where "an exclusive oil-impregnated overlay is laminated to the hardboard surface under heat and pressure." The method of advertising or display of merchandise, while not determinative of classification, does have probative value. *Davis Products, Inc. v. United States,* 59 Cust. Ct. 226, 230, C.D. 3127 (1967). *New York Merchandise Co., Inc. v. United States,* 62 Cust. Ct. 38, 44, C.D. 3671 (1969). *Montgomery Ward & Co. v. United States,* 62 Cust. Ct. 718, 724, C.D. 385 (1969). The product undergoes a separate manufacturing step so that the newsprint layer can be added, thereby providing a quality enhancing characteristic not otherwise available in hardboard. The advertising literature has probative value supporting the conclusion that the subject hardboard lap siding is a laminated board.

One commenter presents expert testimony to support the conclusion that the product is not laminated. The expert witness defines a laminate as a structure that consists of (1) dissimilar finished materials that are fused together or bonded by means of an adhesive and that constitute distinct visible layers of comparable thicknesses, or (2) similar finished materials that are bonded together by means of an adhesive that constitutes distinct visible layers of comparable thicknesses. This definition is claimed to be accepted by the building industry as well as by scientific and academic communities. The layers must be visually distinguishable either to the unaided eye, or microscopically.

The common and commercial definitions of "laminate" do not support the conclusion that a laminate must have distinct visible layers of comparable thicknesses. The expert witness has admitted that he is unaware of any definition of laminate, other than his own, that contains the "comparable thickness" requirement. This fact contradicts his claim that his definition is accepted by the general public and building materials industry as well as by the academic and scientific communities.

Customs believes that the expert testimony is of limited value and does not serve to enhance the understanding of the definition of "laminated" as it applies to building boards.

The legislative history of item 245.80, TSUS, as noted by one commenter, indicates the intent of Congress in enacting the provision. The U.S. Tariff Commission, *Tariff Classification Study; Schedule 2—Wood and Paper* (November 15, 1960), page 64, notes:

> Most hardboard is presently classified in Paragraph 1413. However, if its surface is covered with a laminate of synthetic resin and paper, it is classifiable in Paragraph 1403 as a manufacture of pulp if in chief value of hardboard or in Paragraph 1539(b) if in chief value of the laminate.

The subject product is covered with a laminate of synthetic resin and paper. Both paragraphs 1403 and 1539(b) are cited in the *Tariff Classification Study* as sources for item 245.80, TSUS. Accordingly, Customs believes that the legislative history of item 245.80, TSUS, supports the conclusion that the subject product is classifiable under that item number.

Two commenters, one supporting the item 245.80, TSUS, laminated board

classification and one opposing, cite judicial precedent as supporting their respective positions. In *United States* v. *O.M. Baxter (Inc.)*, 16 Cust. Ct. 257, T.D. 42868 (1928), the court supports the proposition that laminated products are composed of laminae or layers.

In *Crown Abrasive Co., Inc.* v. *United States*, 34 Cust. Ct. 347, Abs. 58990 (1955), the court found a grinding disc to be laminated even though an expert witness admitted that the layers which formed the disc could not be discerned visually.

In *Sommers Plastic Products Co.* v. *United States*, 58 Cust. Ct. 409, C.D. 3002 (1967), the court found a three-layered polyvinly chloride sheeting material with a middle layer of foamed polyvinyl chloride resin to be a laminated product. At the time of manufacture of the product, the layer is applied as a foam, to later harden to a synthetic resin. The court referred to the foaming synthetic resin as a middle layer. Accordingly, a layer need not be in finished form at the time of construction in order for the finished product to be classifiable as a laminate. The *Crown Abrasive* and *Sommers* decisions contradict the definition offered by the expert witness which would require a laminate to be constructed of visually discernible layers of finished materials.

One commenter cites various administrative rulings, including Customs New York Ruling Letter dated March 8, 1981 (No. 800125), Customs Ruling Letter dated June 1, 1979 (No. 060298), and T.D. 67–6(4), as supporting the position that the subject lap siding is not laminated. However, these rulings confirm that the provisions of item 245.80, TSUS, apply to products that are laminated because of the presence of a synthetic resin bond.

Decision

After careful analysis of the comments submitted, and further review of the matter, Customs finds that the subject hardboard lap siding, which is manufactured through a process whereby a newsprint face is overlaid on a wet wood fiber mat and combined with the mat through the application of heat and pressure, is classifiable as a building board, not specially provided for, whether or not face finished: laminated boards, bonded in whole or in part, or impregnated, with synthetic resins, under item 245.80, TSUS, dutiable at the rate of 1.4 cents per pound plus 2.6 percent ad valorem. By letter dated May 19, 1986, this decision was reported to the Court of International Trade.

Drafting Information

The principal author of this document was Larry L. Burton, Regulations Control Branch, U.S. Customs Service. However, personnel from other offices participated in its development.

William von Raab,

Commissioner of Customs.

Approved.

Michael H. Lane,

Acting Assistant Secretary of the Treasury.

[FR Doc. 86–24312 Filed 10–27–86; 8:45 am]

BILLING CODE 4820–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 85C–0377]

Listing of Color Additives for Coloring Contact Lenses

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to delete the current limitation on the level of [phthalocyaninato(2-)] copper used in coloring contact lenses. This action responds to a petition filed by Wesley-Jessen, Division of Schering Corp.

DATES: Effective November 28, 1986, except as to any provisions that may be stayed by the filing of proper objections: objections by November 28,1986.

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

FOR FURTHER INFORMATION CONTACT: Mary J. Stephens, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION:

I. Intoduction

In a notice published in the Federal Register of September 19, 1985 (50 FR 38036), FDA announced that a color additive petition (CAP 5C0196) had been filed by Wesley-Jessen, Division of Schering Corp., 37 South Wabash Ave., Chicago, IL 60603, proposing that Part 74 of the color additive regulations (21 CFR Part 74) be amended to provide for the safe use of [phthalocyaninato(2-)] copper as a color additive in coloring contact lenses. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376). Since the filing of the petition, Wesley-Jessen has changed its address to 400 West Superior St., Chicago, IL 60610.

II. Analysis of Data

In the Federal Register of August 2, 1983 (48 FR 34946), FDA listed [phthalocyaninato(2-)] copper for use in contact lenses at levels not to exceed 0.01 percent by weight of the contact lens material. In that document, the agency stated that the available evidence did not support the safety of the use of the color additive in contact lenses at higher levels.

Wesley-Jessen has now petitioned the agency to remove the limitation on the amount of [phthalocyaninato(2-)] copper that may be used to color contact lenses. In support of this petition, the petitioner submitted the results of an in vitro cytotoxicity study that was performed by directly exposing cultured mammalian cells to graded concentrations (0.01 to 0.06 percent) of [phthalocyaninato(2-)] copper. No cytotoxic responses were noted under the conditions of the test, even at the highest (0.06 percent) level tested.

Based on this data and on the other information available to the agency, FDA has concluded that it can amend § 74.3045 to eliminate the 0.01 percent limitation in the use of [phthalocyaninato(2-)] copper in contact lenses. The agency estimates, based on the data submitted by the petitioner and on other relevant information, that the upper limit of exposure to [phthalocyaninato(2-)] copper from its use in coloring contact lenses is 280 nanograms per day. The agency calculated this upper limit of exposure based on several factors. First, FDA estimated that the maximum use level of [phthalocyaninato(2-)] copper is 50 micrograms per lens. (See memorandum of February 19, 1985, from Food Additive Chemistry Evaluation Branch to Petitions Control Branch, Re: Color Additives in Contact Lenses, which is on file in the Dockets Management Branch (address above) under the docket number appearing in the heading of this document and is available for public review between 9 a.m. to 4 p.m., Monday through Friday.) Second, the agency made two worst case assumptions: (1) That the user will replace lenses tinted with the color additive once each year with a new pair of lenses tinted with the color additive at the maximum use level; and (2) that 100 percent of the color additive migrates from the lenses over the 1-year period. Because these assumptions are worst case, exposure to

[phthalocyaninato(2-)] copper from use in contact lenses is likely to be far less than 280 nanograms per day.

For example, in the lenses covered by the petition before the agency, the amount of [phthalocyaninato(2-)] copper added is usually 0.02 percent by weight of the contact lens material. If lenses weighing 33 milligrams each (the weight of the lens in the petition) are tinted with 0.02 percent [phthalocyaninato(2-)] copper, there would be approximately 6.6 micrograms of [phthalocyaninato(2-)] copper in each lens or approximately 13 micrograms in a pair of lenses. If 100 percent of the color additive migrated to the eye from the lenses in 1 year, the wearer would be exposed to approximately 36 nanograms of [phthalocyaninato(2-)] copper per day.

Based on the results of the cytotoxicity studies submitted by the petitioner, FDA finds that it can conclude to a reasonable certainty that no harm will result from the use of [phthalocyaninato(2-)] copper, even if no limits are set on the levels of that use. The finding of no cytotoxic effect at the 0.06 percent level of the color additive represents a safety margin of approximately 56,000 times the concentration that would be in the eyes if 36 nanograms of the additive migrated into the eyes per day. Moreover, it is 7,000 times the concentration that would be in the eyes if 280 nanograms (the worst case exposure) of the color additive migrated into the eye per day.

To ensure the safe use of [phthalocyaninato(2-)] copper, however, FDA is amending § 74.3045 to state that this color additive may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

III. Conclusion

Based on the data contained in the petition and other relevant material, FDA concludes that the safety margin for use of this color additive is large enough to rule out any need for imposing a limitation on the amount of the color additive that may be present in the lens, beyond the limitation that only that amount necessary to accomplish the intended technical effect may be used. The agency further concludes, on the basis of data contained in the petition and other relevant data, that there is a reasonable certainty that no harm will result from the petitioned use of [phthalocyaninato(2-)] copper, and that this color additive is suitable for its intended use. The agency, therefore, is amending the color additives regulations by deleting the current limitation on the use of this color additive in contact lenses.

V. Inspection of Documents

In accordance with § 71.15(a) (21 CFR 71.15(a)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. As provided in § 71.15(b), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VI. Environmental Assessment

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Under FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25), an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(2).

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before November 28, 1986 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register.**

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 74 is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 74 continues to read as follows:

Authority: Secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10.

2. Section 74.3045 is amended by revising paragraph (c)(2) to read as follows:

§ 74.3045 [Phthalocyaninato(2-)] copper.

* * * * *

(c) * * *

(2) The color additive [phthalocyaninato(2-)] copper may be safely used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

* * * * *

Dated: October 21, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-24273 Filed 10-27-86; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 178

[Docket No. 86N-0277]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Editorial Amendment; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that amended the food additive regulations by removing certain limitations on the use of an additive as a component of olefin polymers intended to contact food. This document corrects a typographical error.