analyzing small entity impact for purposes of the Regulatory Flexibility Act, we believe that, to the extent that the rule impacts small air carriers, the impact will be a favorable one, since it will consist of receiving compensation. We have facilitated the participation of small entities in the program by allowing a longer application period for indirect air carriers, wet lessors and air taxis, which are generally the smallest carriers covered by this rule and which generally do not otherwise report traffic or financial data to the Department. The Department has also concluded that this rule does not have sufficient Federalism implications to warrant the consultation requirements of Executive Order 13132.

We are making this rule effective immediately, without prior opportunity for public notice and comment. Because of the need to move quickly to provide compensation to air carriers for the purpose of maintaining a safe, efficient, and viable commercial aviation system in the wake of the events of September 11, 2001, prior notice and comment would be impractical, unnecessary, and contrary to the public interest. Consequently, prior notice and comment under 5 U.S.C. 553 and delay of the effective date under 5 U.S.C. 801, *et seq.*, are not being provided. On the same basis, we have determined that there is good cause to make the rule effective immediately, rather than in 30 days.

The Office of Management and Budget has approved the information collection requirements of this rule, with Control Number 2105–0546.

List of Subjects in 14 CFR Part 330

Air carriers, Grant programs—transportation, Reporting and recordkeeping requirements.

Issued this 30th day of January, 2002, at Washington, DC.

Read C. Van de Water,

Assistant Secretary for Aviation and International Affairs.

For the reasons set forth in the preamble, the Department amends 14 CFR part 330 as follows:

PART 330—PROCEDURES FOR COMPENSATION OF AIR CARRIERS

1. Authority citation for Part 330 continues to read as follows:

Authority: Pub. L. 107–42, 115 Stat. 230 (49 U.S.C. 40101 note); sec. 124(d), Pub. L. 107–71, 115 Stat. 631 (49 U.S.C. 40101 note).

2. Revise § 330.21(d) introductory text to read as follows:

§ 330.21 When must air carriers apply for compensation?

* * * * *

(d) Notwithstanding any other provision of this section, if you are an eligible air carrier that did not submit an application or wishes to amend its application, you may do so by February 8, 2002 if you are one of the following:

* * * * *

[FR Doc. 02–2652 Filed 1–30–02; 4:57 pm]

BILLING CODE 4910–62–P

FEDERAL TRADE COMMISSION

16 CFR Part 303

Rules and Regulations Under the Textile Fiber Products Identification Act

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''Commission'') announces amendments to rule 7 of the Rules and Regulations Under the Textile Fiber Products Identification Act (''Textile Rules''), to designate a new generic fiber name and establish a new generic fiber definition for a fiber manufactured by Cargill Dow, LLC (''Cargill Dow'') of Minnetonka, Minnesota. The amendments create a new subsection (y) to Rule 7 that establishes the name ''PLA'' for a fiber that Cargill Dow designates by the registered name ''Natureworks.''

EFFECTIVE DATE: February 1, 2002.

FOR FURTHER INFORMATION CONTACT: Neil Blickman, Attorney, Division of Enforcement, Federal Trade Commission, Washington, DC 20580; (202) 326–3038.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory and Regulatory Framework

Section 4(b)(1) of the Textile Fiber Products Identification Act (''Act'') declares that a textile product will be misbranded unless it is labeled to show, among other elements, the percentages, by weight, of the constituent fibers in the product, designated by their generic names and in order of predominance by weight. 15 U.S.C. 70b(b)(1). Section 4(c) of the Act provides that the same information required by section 4(b)(1) (except the percentages) must appear in written advertisements if any disclosure or implication of fiber content is made regarding a covered textile product. 15 U.S.C. 70b(c). Section 7(c) directs the Commission to promulgate such rules, including the establishment of generic names of manufactured fibers, as are necessary to enforce the Act's directives. 15 U.S.C. 70e(c).

Rule 6 of the Textile Rules requires manufacturers to use the generic names of the fibers contained in their textile fiber products in making required disclosures of the fiber content of the products. 16 CFR 303.6. Rule 7 sets forth the generic names and definitions that the Commission has established for synthetic fibers. 16 CFR 303.7. Rule 8 sets forth the procedures for establishing new generic names. 16 CFR 303.8.

B. Procedural History

On August 28, 2000, Cargill Dow applied to the Commission for a new fiber name and definition.[1] Its application states that PLA fibers are synthetic but are derived from natural renewable resources (agricultural crops such as corn).[2] It maintained that PLA can combine certain advantages of natural fibers with those of certain synthetic fibers. Cargill Dow contended that its proprietary Natureworks PLA fiber, and PLA that may be made using alternative processes, have unique properties that, along with PLA's unique fundamental chemistry, differentiate PLA fibers from all other recognized and listed synthetic or natural fibers.

Contending that the unique chemistry of fibers made from PLA is inadequately described under existing generic names listed in the Textile Rules, Cargill Dow petitioned the Commission to establish a new generic name and definition. After an initial analysis, the Commission announced, on October 30, 2000, that it had issued Cargill Dow the designation ''CD 0001'' for temporary use in identifying PLA fiber pending a final determination as to the merits of the application for a new generic name and definition. The Commission staff further analyzed the application, and on November 17, 2000 (65 FR 69486), the Commission published a Notice of Proposed Rulemaking (''NPR'') detailing the technical aspects of Cargill Dow's fiber, and requesting public comment on Cargill Dow's application. On January 29, 2001, the comment period closed.

[1] This petition and additional information that Cargill Dow submitted are on the rulemaking record of this proceeding. This material, as well as the comments that were filed in this proceeding, are available for public inspection in accordance with the Freedom of Information Act, 5 U.S.C. 552, and the Commission's Rules of Practice, 16 CFR 4.11, at the Consumer Response Center, Public Reference Section, Room 130, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC. The comments that were filed are found under the Rules and Regulations Under the Textile Fiber Products Identification Act, 16 CFR part 303, Matter No. P948404, ''Cargill Dow Generic Fiber Petition Rulemaking.'' The comments also are available for viewing in electronic form at <<www.ftc.gov>>.

[2] PLA also is the acronym for the polymer from which the fiber is manufactured, namely polylactic acid or polylactide.

II. Description of the Fiber and Solicitation of Comments in the NPR

A. The Commission's Criteria for Granting a New Generic Fiber Name and Definition, and Related Issues

In the NPR, the Commission solicited comment on whether Cargill Dow's application meets the Commission's three criteria for granting petitions for new generic names:

1. The fiber for which a generic name is requested must have a chemical composition radically different from other fibers, and that distinctive chemical composition must result in distinctive physical properties of significance to the general public.

2. The fiber must be in active commercial use or such use must be immediately foreseen.

3. The grant of the generic name must be of importance to the consuming public at large, rather than to a small group of knowledgeable professionals such as purchasing officers for large government agencies.[3]

In the NPR, the Commission noted that repeat units of PLA are linked by ester groups, which means that PLA fiber is a polyester. The Commission agreed with Cargill Dow, however, that PLA does not fit into Rule 7's current definition of polyester. Therefore, the Commission requested public comment on whether to: (1) Broaden Rule 7's definition of polyester to include PLA fiber; (2) create a separate subcategory and definition for PLA fiber within Rule 7's definition of polyester; or (3) add a new generic fiber name and definition to Rule 7 for PLA fiber.

B. The NPR

1. Fiber Description and Proposed Name and Definition

The NPR provided a detailed description, taken from Cargill Dow's application, of PLA's chemical composition and physical and chemical properties.[4] Cargill Dow explained that PLA fibers typically are made using lactic acid as the starting material for polymer manufacture. The lactic acid comes from fermenting various sources of natural sugars. These sugars can come from annually renewable agricultural crops such as corn or sugar beets. Cargill Dow maintained that PLA's fundamental polymer chemistry allows control of certain fiber properties and makes the fiber suitable for a wide variety of technical textile fiber applications, especially apparel and performance apparel applications. Of most significance to consumers, Cargill Dow maintained that PLA fibers exhibit: (1) Low moisture absorption and high wicking, offering benefits for sports and performance apparel and products; (2) low flammability and smoke generation; (3) high resistance to ultra violet (UV) light, a benefit for performance apparel as well as outdoor furniture and furnishings applications; (4) a low index of refraction, which provides excellent color characteristics; and (5) lower specific gravity, making PLA lighter in weight than other fibers. In addition to coming from an annually renewable resource base, Cargill Dow stated that PLA fibers are readily melt-spun, offering manufacturing advantages that will result in greater consumer choice.

In the NPR, the Commission proposed the following fiber name and definition for PLA, which Cargill Dow had suggested:

> Synterra. A manufactured fiber in which the polymer is produced either (a) by the condensation of lactic acid or (b) by ring opening of the cyclic dimer, lactide, in both cases where at least 85% of the primary component is derived from a renewable resource as an integral part of the polymer chain.

In proposing this definition, the Commission noted Cargill Dow's statement that PLA used to make the fiber can be polylactic acid or polylactide. According to the company, although the lactide intermediate route used by Cargill Dow has proven most effective, direct condensation of lactic acid also will result in PLA.

2. Discussion of the Public Comments

The NPR elicited eight comments, including one from Cargill Dow.[5] Four commenters, Dystar UK Ltd, the National Corn Grower's Association, the Interface Research Corporation, and the Woolmark Company, as well as Cargill Dow, fully supported amending the Textile Rules to create a new, separate category in Rule 7 for PLA fiber and establishing a new generic fiber name and definition for Cargill Dow's fiber, as proposed by the Commission.[6] Two other commenters supported creating a new name and definition for PLA fiber, but had comments about the name and definition proposed in the NPR, as discussed below. Only one commenter, FSA, opposed creating a new name and definition for PLA.

FSA stated that PLA's physical properties and processing behavior indicate that it should be regarded as merely an advanced type of polyester with several benefits for the environment. In the NPR, although the Commission noted that the repeat units of PLA are linked by ester groups like polyester fibers, the Commission tentatively concluded that PLA fiber did not fit into the current definition for polyester in Rule 7.[7] PLA is an aliphatic polyhydroxycarboxylic acid, unlike other polyester fibers. In addition, PLA has a distinctly lower melting point and specific gravity than polyester fibers. It also appears to have better flame resistance qualities than polyester fibers. In light of PLA's unique chemical and physical properties, as well as seven other public comments, including the petitioner's, that supported creating a separate category in Rule 7 for PLA fiber, the Commission has determined not to amend the Rule to broaden the current definition for polyester in section 7(c) of the Rule to include PLA fiber.

With respect to the proposed name ''synterra,'' AFMA commented that as a result of two other commercial names now in use, consumer confusion could occur if the Commission adopted the proposed name. AFMA pointed out that ''sontara'' and ''sensura'' are trade names currently used by DuPont and Wellman Fibers, respectively, that apply to fibers, fabrics, and end-product uses similar to the anticipated uses for PLA fiber. The EC also commented that the proposed name, ''synterra,'' lacks sufficient reference to the chemical composition or physical properties of the fiber, and gives the impression of being a commercial trade name.

Finally, with respect to the new generic fiber definition, AFMA commented that the definition established by the Commission should be limited to a description of the fiber's chemical composition and should not include the method of manufacture.

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[3] The Commission first announced these criteria on December 11, 1973 (38 FR 34112), and later clarified and reaffirmed them on December 6, 1995 (60 FR 62352), May 23, 1997 (62 FR 28342), and January 6, 1998 (63 FR 447 and 63 FR 449).

[4] 65 FR 69486, at 69487–69491 (Nov. 17, 2000). For brevity's sake, the Commission is providing a simplified description of the fiber in this notice, and refers those who wish to see detailed technical information about the fiber to the earlier description in the NPR.

[5] (1) American Fiber Manufacturers Association, Inc. (''AFMA''); (2) Dystar UK Ltd; (3) Keller and Heckman LLP on behalf of Cargill Dow; (4) National Corn Growers Association; (5) Interface Research Corporation; (6) Woolmark Company; (7) Finnish Standards Association (''FSA''); and (8) European Commission (''EC'').

[6] Cargill Dow's comment provides the Commission with the results of the consumer focus group research it sponsored. The report demonstrated that the focus group participants believed it would be most appropriate to place PLA in a separate fiber category.

[7] 65 FR 69486 (Nov. 17, 2000).

3. Discussion of the Three Criteria for Granting New Generic Names

a. Distinctive Chemical Composition and Physical Properties of Importance to the Public

The materials Cargill Dow submitted show that PLA fiber is based upon a distinctive chemical structure that is not encompassed by any existing definition in Rule 7. PLA's distinctive chemical structure results in a fiber that exhibits: low moisture absorption and high wicking, low flammability, high resistance to ultra violet light, a low index of refraction, and stability with respect to laundering and dry cleaning. In addition, the fiber comes from a renewable resource base. These properties are very important to those members of the general public who, for example, desire sports or performance apparel that is water-resistant and washable, or desire furnishings with low flammability. Thus, Cargill Dow's application meets this first criterion.

b. Active Commercial Use

Cargill Dow's petition stated that fibers produced from PLA have been made into finished goods that are ready to commercialize, and several are in test markets. When it filed its petition, Cargill Dow was in the process of building a plant in Blair, Nebraska, capable of producing approximately 30 million pounds per year of PLA. Counsel for Cargill Dow has informed Commission staff that the plant soon will be operational. Such a level of production for distribution satisfies this second criterion.

c. Importance to the Consuming Public

The Commission agrees with Cargill Dow that the granting of a generic name to describe PLA is of importance to the general public, and not just a few knowledgeable professionals such as purchasing officers for large government agencies. A new generic name will enable consumers to identify textile fiber products containing PLA (such as sports and performance apparel) that exhibit significant water-resistance, softer feel or ''hand,'' elasticity, shape retention, and improved comfort. Thus, Cargill Dow's application satisfies this third criterion.

4. Conclusion

Based on the foregoing, the Commission finds that Cargill Dow's fiber, PLA, is of a distinctive chemical composition not encompassed by any of the Textile Rules' existing generic definitions for manufactured fibers, that its physical properties are important to the public, that the fiber is in active commercial use, and that the granting of a new generic name and definition is important to the consuming public at large.

In light of the comments it received, the Commission has determined to adopt the generic name ''PLA'' to identify Cargill Dow's new manufactured fiber. The name ''PLA'' is used throughout Cargill Dow's application to identify its Natureworks fiber, and there is a precedent in the Rule, namely ''PBI,'' for adopting an acronym as a generic fiber name (16 CFR 303.7(u)). In addition, the Commission is not aware of any other aliphatic hydroxycarboxylic acid derived polymer currently being used to manufacture textile fibers. Accordingly, to avoid consumer confusion, and in the absence of any other suggested generic fiber names from the commenters or the petitioner, the Commission has determined to designate the generic name ''PLA'' for Cargill Dow's Natureworks fiber.

Further, the Commission agrees that it would be inappropriate to include methods of manufacture in the new generic fiber definition of PLA. There is no precedent for doing so in section 303.7 of the Rule, and, in the Commission's view, including methods of manufacture in the generic fiber definition would unduly limit industry research and innovation. Therefore, as a logical outgrowth of the fiber definition proposed in the NPR, the Commission has determined to define PLA generically in terms of its chemical composition.

Accordingly, in light of the materials and information submitted by Cargill Dow, as well as the public comments received during this proceeding, the Commission amends Rule 7 of the Textile Rules by adding the following new name and definition for Cargill Dow's fiber: PLA. A manufactured fiber in which the fiber-forming substance is composed of at least 85% by weight of lactic acid ester units derived from naturally occurring sugars.[8]

III. Effective Date

The Commission is making the amendments effective on February 1, 2002, as permitted by 5 U.S.C. 553(d), because the amendments do not create new obligations under the Rule; rather, they merely create a fiber name and definition that the public may use to comply with the Rule.

[8] The Commission notes that the definition of PLA it is adopting is consistent in form with, for example, the definition of Azlon, which is defined as a manufactured fiber in which the fiber-forming substance is composed of any regenerated naturally occurring proteins (16 CFR 303.7(g)).

IV. Regulatory Flexibility Act

In the NPR, the Commission tentatively concluded that the provisions of the Regulatory Flexibility Act relating to an initial regulatory analysis, 5 U.S.C. 603–604, did not apply to the proposal because the amendments, if promulgated, would not have a significant economic impact on a substantial number of small entities. The Commission believed that the proposed amendments would impose no additional obligations, penalties, or costs. The amendments simply would allow covered companies to use a new generic name for a new fiber that may not appropriately fit within current generic names and definitions, and would impose no additional labeling requirements. To ensure, however, that no substantial economic impact was overlooked, the Commission solicited public comment in the NPR on the effects of the proposed amendments on costs, profits, competitiveness of, and employment in small entities. 65 FR 69486, at 69491 (Nov. 17, 2000).

No comments were received on this issue. Accordingly, the Commission hereby certifies, pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605(b), that the amendments promulgated today will not have a significant economic impact on a substantial number of small entities.

V. Paperwork Reduction Act

These amendments do not constitute ''collection[s] of information'' under the Paperwork Reduction Act of 1995, Pub. L. 104–13, 109 Stat. 163, 44 U.S.C. Chapter 35 (as amended), and its implementing regulations, 5 CFR 1320 *et seq.* Those procedures for establishing generic names that do constitute collections of information, 16 CFR 303.8, have been submitted to OMB, which has approved them and assigned them control number 3084–0101.

List of Subjects in 16 CFR Part 303

Labeling, Textile, Trade practices.

VI. Text of Amendments

For reasons set forth in the preamble, 16 CFR Part 303 is amended as follows:

PART 303—RULES AND REGULATIONS UNDER THE TEXTILE FIBER PRODUCTS IDENTIFICATION ACT

1. The authority citation for part 303 continues to read as follows:

Authority: Sec. 7(c) of the Textile Fiber Products Identification Act (15 U.S.C. 70e(c)).

2. In § 303.7, paragraph (y) is added, to read as follows:

§ 303.7 Generic names and definitions for manufactured fibers.

* * * * *

(y) *PLA.* A manufactured fiber in which the fiber-forming substance is composed of at least 85% by weight of lactic acid ester units derived from naturally occurring sugars.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 02–2434 Filed 1–31–02; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 201, 250, 290, 310, 329, 341, 361, 369, 606, and 610

[Docket No. 00N–0086]

Amendment of Regulations Regarding Certain Label Statements on Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations concerning certain statements that have been required on the labels of prescription drugs generally and on certain narcotic or hypnotic (habit-forming) drugs. The agency is taking this action in accordance with provisions of the Food and Drug Administration Modernization Act of 1997 (Modernization Act).

DATES: This rule is effective April 2, 2002.

FOR FURTHER INFORMATION CONTACT:

For information regarding human drugs: Jerry Phillips, Center for Drug Evaluation and Research (HFD–400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3246.

For information regarding biologics: Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the Modernization Act (Public Law 105–115) was signed into law. Section 126 of the Modernization Act amended section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(b)(4)) to require, at a minimum, that, prior to dispensing, the label of prescription drugs bear the symbol ''Rx only'' instead of the statement ''Caution: Federal law prohibits dispensing without prescription.'' The new label statement may be printed as either ''Rx only'' or ''℞ only.'' Section 126 of the Modernization Act also repealed section 502(d) of the act (21 U.S.C. 352(d)), which provided that a drug or device containing certain enumerated narcotic or hypnotic (habit-forming) substances or their derivatives was misbranded unless its label bore the name and quantity of the substance and the statement ''Warning—May be habit forming.'' In the **Federal Register** of April 21, 2000 (65 FR 21378), FDA proposed amending its regulations to implement these provisions of the Modernization Act.

II. Highlights of the Final Rule

The agency is finalizing without change the regulatory provisions of the proposed rule.

- The final rule amends parts 10, 201, 250, 310, 329, 361, 606, and 610 (21 CFR parts 10, 201, 250, 310, 329, 361, 606, and 610) by removing the requirement that prescription drugs be labeled with ''Caution: Federal law prohibits dispensing without prescription'' and adding in its place a requirement that prescription drugs be labeled with ''Rx only'' or ''℞ only.''
- The final rule amends parts 201 and 369 (21 CFR part 369) by removing the requirement that certain habit-forming drugs bear the statement ''Warning—May be habit forming.''
- The final rule removes part 329, Habit-Forming Drugs.
- The final rule amends part 290 (21 CFR part 290) by adding new §§ 290.1 and 290.2. Section 290.1 is being added to make clear the agency's determination that a drug that is a controlled substance listed in schedule II, III, IV, or V of the Federal Controlled Substances Act (CSA) or implementing regulations must, unless otherwise determined by the agency, be dispensed by prescription only as required by section 503(b)(1) of the act. Section 290.2 retains the exemption from the prescription-dispensing requirement in § 329.20 for small amounts of codeine in combination with other nonnarcotic active medicinal ingredients.

III. Comments on the Proposed Rule

The agency received three comments from pharmaceutical companies and one comment from an association of pharmacists.

(1). All four comments concerned the appearance of the ''Rx only'' statement on the label. In the proposed rule, the ℞ symbol appeared in bold because of type-setting limitations. FDA did not want to create the impression that it was proposing to require the ℞ symbol to appear in bold. In an attempt at clarification, a footnote was included in the proposed rule stating: ''The ℞ symbol appears in bold in this document because of type-setting limitations, however, it should not be bolded when used on the product's label'' (65 FR 21378). Two comments objected to this apparent prohibition against the use of bolding, noting that the implementing guidance discussed in section IV of this document did not prescribe whether or not the ℞ symbol or the Rx only statement generally should appear in bold. FDA agrees with these comments. The ℞ symbol and the Rx only statement may be printed in bold or in regular type.

(2). In the implementing guidance, FDA stated: ''The statement should be prominent and conspicuous, as is required by section 502(c) of the Act and 21 CFR 201.15.'' One comment suggested that manufacturers should not be permitted to determine what placement on the label is prominent and conspicuous. The comment asked that FDA require that the Rx only statement appear on the main part of the label and also that FDA establish a minimum font size for the Rx only statement relative to the other text on the label.

FDA declines to adopt this suggestion. Section 502(c) of the act provides that a drug or device is misbranded if a label statement required by the act or FDA regulations * * * ''is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.'' FDA's regulation at § 201.15 elaborates on specific factors that could render a label statement not prominent and conspicuous. This regulation applies to the Rx only statement, and thus requirements specific to the Rx only statement are unnecessary.

(3). One comment objected to the agency's position, expressed in the implementing guidance, that manufacturers are not prohibited from using the ''Warning—May be habit forming'' statement. The Modernization Act removed the requirement that the labels of habit-forming drugs bear this statement, but did not prohibit use of the statement. However, as explained in