

and Budget (OMB) Control Number. This rule covers collections of information subject to the provisions of the PRA. The OMB has approved this collection and assigned to it OMB Control Number 0608-0009. The collection will display this control number.

An estimated 3,950 U.S. affiliates are expected to file responses quarterly, or 15,800 responses annually. The average burden for completing the BE-605 and BE-605 Bank remains unchanged at 1.25 hours per response, per quarter (five hours per year); the total annual respondent burden, from the current OMB inventory, also remains unchanged at 19,750 hours (15,800 responses times 1.25 hours average burden). This estimate covers the amount of time for respondents to review the instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. The burden estimates used in this submission are based upon experience with the same quarterly survey forms for several years and upon the burden estimates developed at the time of the benchmark survey.

Comments regarding the burden estimate or any other aspect of this collection of information should be addressed to: Director, Bureau of Economic Analysis (BE-1), U.S. Department of Commerce, Washington, DC 20230; and to the Office of Management and Budget, O.I.R.A., Paperwork Reduction Project 0608-0009, Washington, DC 20503 (Attention PRA Desk Officer for BEA).

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, certified to the Chief Counsel for Advocacy, Small Business Administration, under the provisions of the Regulatory Flexibility Act (RFA) (5 U.S.C. 605(b)), that this final rule will not have a significant economic impact on a substantial number of small entities. Few, if any, small U.S. businesses are subject to the reporting requirements of this survey. Most small businesses are not foreign owned; those that are and have total assets, sales or gross operating revenues, and net income each equal to or less than \$30 million are not required to report on the BE-605 or BE-605 Bank form. Accordingly, this action will relieve reporting burdens on small entities.

List of Subjects in 15 CFR Part 806

International transactions, economic statistics, foreign investment in the

United States, penalties, reporting and recordkeeping requirements.

Dated: January 3, 2003.

J. Steven Landefeld,

Director, Bureau of Economic Analysis.

For the reasons set forth in the preamble, BEA amends 15 CFR part 806 as follows:

PART 806—DIRECT INVESTMENT SURVEYS

1. The authority citation for 15 CFR Part 806 continues to read as follows:

Authority: 5 U.S.C. 301; 22 U.S.C. 3101-3108; and E.O. 11961 (3 CFR, 1977 Comp., p. 86), as amended by E.O. 12013 (3 CFR, 1977 Comp., p. 147), E.O. 12318 (3 CFR, 1981 Comp., p. 173), and E.O. 12518 (3 CFR, 1985 Comp., p. 348).

2. Section 806.15(h)(1) and (2) are revised to read as follows:

§ 806.15 Foreign direct investment in the United States.

* * * * *

(h) * * *

(1) BE-605—Transactions of U.S. Affiliate, Except a U.S. Banking Affiliate, With Foreign Parent: One report is required for each U.S. affiliate exceeding an exemption level of \$30,000,000, that does not qualify for reporting on form BE-605 Bank.

(2) BE-605 Bank—Transactions of U.S. Banking Affiliate with Foreign Parent: One report is required for each U.S. banking affiliate or U.S. bank holding company affiliate, including all of the subsidiaries and units of the bank holding company, exceeding an exemption level of \$30,000,000.

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[FR Doc. 03-1770 Filed 1-24-03; 8:45 am]

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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(m) of the Rules and Regulations Under the Textile Fiber Products Identification Act (“Textile Rules”) to establish a new generic fiber subclass name and definition for a subclass of olefin fibers manufactured by the Dow Chemical Company (“Dow”), of Midland,

Michigan. The amendments to rule 7(m) establish the subclass name “lastol” as an alternative to the generic name “olefin” for a specific subclass of elastic, cross-linked textile fibers defined in the amendments, and previously referred to by Dow as “CEF.”

EFFECTIVE DATE: January 27, 2003.

FOR FURTHER INFORMATION CONTACT: Neil Blickman, Attorney, Division of Enforcement, Bureau of Consumer Protection, 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 (16 CFR 303.6) requires manufacturers to use the generic names of the fibers contained in their textile products in making required fiber content disclosures on labels. Rule 7 of the Textile Rules (16 CFR 303.7) sets forth the generic names and definitions that the Commission has established for synthetic fibers. Rule 8 (16 CFR 303.8) describes the procedures for establishing new generic names.

B. Procedural History

Dow applied to the Commission on October 18, 2001, for a new olefin fiber subclass name and definition, and supplemented its application with additional information and test data on December 12, 2001, January 16, 2002, and March 19, 2002.¹ Dow stated that its

¹ Dow’s petition and supplements thereto are on the rulemaking record of this proceeding. This material is 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 petition also may be viewed on the Commission’s website at www.ftc.gov.

new cross-linked elastic fiber, CEF, is a manufactured olefin textile fiber with a cross-linked polymer network structure. Dow stated that CEF meets the broad definition of olefin fiber in the Textile Rules, 16 CFR 303.7(m), but differs from commercially available olefin fibers because of its elasticity and wide temperature tolerance, and thus is a good choice for easy-care stretch apparel applications.

Contending that the unique structure and characteristics of fibers made from CEF are inadequately described under existing generic names listed in the Textile Rules, Dow petitioned the Commission to establish a new generic subclass name and definition. After an initial analysis with the assistance of a textile expert, the Commission determined that Dow's proposed new fiber technically falls within rule 7(m)'s definition of "olefin."² The Commission further determined, however, that Dow's application for a new subclass name and definition merited further consideration. Accordingly, on May 17, 2002, the Commission announced that it had issued Dow the designation "DCC 0001" for temporary use in identifying CEF fiber pending a final determination on the merits of its application. The Commission staff further analyzed the application, and on May 24, 2002 (67 FR 36551), the Commission published a notice of proposed rulemaking ("NPR") detailing the technical aspects of Dow's fiber, and requesting public comment on Dow's application. On August 12, 2002, the comment period closed.

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

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

In the NPR, the Commission solicited comment on whether Dow's application

² Rule 7(m) defines "olefin" as "[a] manufactured fiber in which the fiber-forming substance is any long chain synthetic polymer composed of at least 85 percent by weight of ethylene, propylene, or other olefin units, except amorphous (noncrystalline) polyolefins qualifying under paragraph (j)(1) of this section." 16 CFR 303.7(m). Rule 7(j)(1) defines "rubber," in part, as "[a] manufactured fiber in which the fiber-forming substance is comprised of natural or synthetic rubber, including the following categories: (1) [a] manufactured fiber in which the fiber-forming substance is a hydrocarbon such as natural rubber, polyisoprene, polybutadiene, copolymers of dienes and hydrocarbons, or amorphous (noncrystalline) polyolefins." 16 CFR 303.7(j)(1). Dow's petition stated that CEF is not a rubber because CEF fibers have a low but significant level of crystallinity, whereas rubber fibers are not crystalline. In addition, CEF exhibits much higher tensile set (lower elastic recovery) than rubber when extended to greater than 100% elongation.

meets the Commission's criteria for granting applications for new generic fiber subclass names. Specifically, does the proposed subclass fiber: (1) Have the same general chemical composition as an established generic fiber category; (2) have distinctive properties of importance to the general public as a result of a new method of manufacture or substantially differentiated physical characteristics, such as fiber structure; and (3) do the distinctive feature(s) make the fiber suitable for uses for which other fibers under the established generic name would not be suited, or would be significantly less well suited?³

Within the established 24 generic names for manufactured fibers, there are four cases where such generic name alternatives may be used: (1) Pursuant to rule 7(c), 16 CFR 303.7(c), within the generic category "polyester," the term "elasterell-p" may be used as an alternative generic description for a specifically defined subcategory of polyester fiber; (2) pursuant to rule 7(d), 16 CFR 303.7(d), within the generic category "rayon," the term "lyocell" may be used as an alternative generic description for a specifically defined subcategory of rayon fiber; (3) pursuant to rule 7(e), 16 CFR 303.7(e), within the generic category "acetate," the term "triacetate" may be used as an alternative generic description for a specifically defined subcategory of acetate fiber; and (4) pursuant to rule 7(j), 16 CFR 303.7(j), within the generic category "rubber," the term "lastrile" may be used as an alternative generic description for a specifically defined subcategory of rubber fiber.

Although the Commission's NPR announced that Dow's fiber technically

³ The criteria for establishing a new generic subcategory are different from the criteria to establish a new generic category. The Commission's criteria for granting applications for new generic names are as follows: (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; and (3) the granting 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. The Commission believes it is in the public interest to prevent the proliferation of generic names, and will adhere to a stringent application of these criteria in consideration of any future applications for generic names, and in a systematic review of any generic names previously granted that no longer meet these criteria. The Commission announced these criteria on Dec. 11, 1973, at 38 FR 34112, and later clarified and reaffirmed them on Dec. 6, 1995, 60 FR 62353, on May 23, 1997, 62 FR 28343, on Jan. 6, 1998, 63 FR 447 and 63 FR 449, and on Nov. 17, 2000, 65 FR 69486, on Feb. 15, 2002, 67 FR 7104, and on May 24, 2002, 67 FR 36551.

falls within rule 7(m)'s definition of olefin, it noted that Dow's application may meet the Commission's standard for a subclass name. Alternatively, the Commission stated that CEF may fit within the current definition of olefin in rule 7(m), with or without need for clarification. Therefore, the Commission requested public comment on whether to: (1) Broaden rule 7(m)'s definition of olefin to better describe the allegedly unique molecular structure and physical characteristics of CEF and any similar fibers (without creating a new subclass for CEF); (2) amend rule 7(m)'s definition of olefin by creating a separate subclass name and definition for CEF and other similar qualifying fibers within the olefin category; or (3) deny Dow's application because CEF fiber fits within rule 7(m)'s definition of olefin without need for any change.

B. The NPR

1. Fiber Description and Proposed Subclass Name and Definition

The NPR provided a detailed description, taken from Dow's application, of CEF's chemical composition and physical and chemical properties.⁴ As a result of CEF's fiber structure, Dow maintained that CEF has the following distinctive properties that would be significant to consumers: (1) Stretch and recovery power that is far superior to that of any olefin fiber; (2) shape retention at temperatures in excess of 170° C, which enables CEF to survive rigorous manufacturing and consumer care processes; and (3) chemical resistance to solvents that typically dissolve conventional olefins. Dow asserted that olefin, widely recognized as a dependable carpet fiber that has no stretch or elastic recovery and poor high temperature stability, is an inappropriate categorization for the elastic olefin fiber, CEF, which is targeted for apparel applications. Dow stated that CEF will offer consumers a wider choice in garments containing stretch fabric, and contended that it would be confusing to consumers if CEF is called simply "olefin."

Dow, therefore, petitioned the Commission to establish the generic name "lastol" as an alternative to, and a subclass of, "olefin." In addition, Dow proposed that the Commission add the following sentence to the current definition of olefin in rule 7(m) to define CEF and similar fibers as a subclass of olefin:

⁴ 67 FR 36551, at 36552-36554 (May 24, 2002). 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 NPR.

Where the fiber is a manufactured cross-linked elastic fiber in which (a) the fiber-forming substance is a synthetic polymer, with low but significant crystallinity, composed of at least 99 percent by weight of ethylene and at least one other olefin unit, and (b) the fiber exhibits substantial elasticity and heat resistance properties not present in traditional olefin fibers, the term lastol may be used as a generic description of the fiber.

The effect of Dow's proposed amendment would be to allow use of the name "lastol" as an alternative to the generic name "olefin" for the subcategory of olefin fibers meeting the further criteria contained in the sentence added by the proposed amendment.

2. Public Comments

The Commission received no comments on the NPR.

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

a. CEF Fiber's Chemical Composition

The Commission has concluded that the materials Dow submitted show that although CEF has the same general chemical composition as other olefin fibers, it also has a molecular and fiber structure that differs from typical olefins. CEF is founded on metallocene-based polyolefin elastomer chemistry and is manufactured using a melt spinning process. After spinning, the fiber is cross-linked in order to prevent dissolution and impart high-temperature dimensional stability. After the cross-linking process, the polymer chains in the fiber are linked to one another via covalent bonds.

The interpolymer⁵ in CEF has been made from ethylene and, typically, octene in excess of 30 weight percent using a constrained geometry catalyst, a member of the metallocene family. The catalyst allows precise control of the molecular architecture of the polymer, which prior to cross-linking has a narrow molecular weight distribution. As a result, the molecules in CEF are very similar in size and composition to each other. In contrast, typical olefin fiber manufactured today results from conventional multi-site catalyst technology (such as Ziegler-Natta catalysts). Consequently, typical olefin fiber has a broad compositional molecular weight distribution, and low or no comonomer content.

As a result of CEF's unique chemical structure, its high comonomer content, CEF has lower crystallinity and density than conventional olefin fibers. Unlike conventional olefin fiber where the

polymer crystals are in lamellae form,⁶ the crystals in the CEF fiber-forming substance are in fringed micelle form.⁷ The fringed micellar crystalline morphology and the low, but significant, level of crystallinity in CEF, which differentiates it from rubber, impart elastic properties not seen in typical olefin fibers. Thus, Dow's application meets the first criterion for granting a new generic fiber subclass name.

b. CEF's Distinctive Properties Are a Result of a New Method of Manufacture or Substantially Differentiated Physical Characteristics, Such as Fiber Structure

1. *Elasticity.* The materials Dow submitted also show that the most notable characteristic (and of greatest importance to consumers) of CEF is its elasticity, which is superior to that of conventional olefin fiber. CEF's favorable stretch (at least five times its original length before breaking) and elasticity (stretching to twice its length and, when released, recovering to within 25 percent of its original length) are a direct result of its low level of crystallinity and its fringed micellar crystal form. As a result, CEF can be successfully used in clothing applications where stretch is desirable.

In contrast, conventional olefin fiber is more stiff and less elastic than CEF. Typical olefin fibers (in their manufactured, "drawn," form) exhibit low elongation before breaking (typically less than 50%) and, therefore, cannot be used as successfully as CEF in apparel markets for stretch clothing.

2. *High Temperature Stability.* CEF's covalent cross-links connect adjacent polymer chains into a contiguous three-dimensional polymer network. Dow's materials show that this cross-linked polymer network structure allows CEF to maintain its shape and mechanical integrity above its crystalline melting temperature.⁸ It appears that CEF retains its shape at temperatures up to 220° C, in excess of conventional olefin's melting point, which occurs at or below 170° C.

CEF's ability to withstand high temperatures has advantages for textile manufacturers who can use dye and process methods requiring temperatures in excess of 170° C. CEF also has advantages for consumers because they will be able to repeatedly wash, dry, and

iron fabrics containing CEF at typical temperatures (up to 210° C) without destroying CEF's stretch properties. In contrast, since conventional olefin fiber loses its shape and mechanical integrity at temperatures ranging from 105–170° C, it cannot withstand as well as CEF the rigors of high heat and repeated launderings.

c. CEF's Distinctive Features Make the Fiber Suitable for Uses for Which Other Olefin Fibers Would Not Be Suited, or Would Be Significantly Less Well Suited

Based on Dow's submission, the Commission has concluded that conventional olefins are not suitable, or not as suitable, for imparting the significant elasticity to certain apparel fabrics, such as knits and wovens, that consumers may expect or desire, and that CEF is a suitable stretch component. Thus, Dow's application has satisfied the Commission that CEF is suitable for uses for which other olefin fibers are not suited, or not as well suited. Accordingly, the Commission agrees with Dow that the granting of a generic subclass name to describe CEF is of importance to the general public, and not just a few knowledgeable professionals. A new generic subclass name will enable consumers to identify textile fiber products containing CEF (and other elastic olefin fibers) that exhibit significant stretch, elasticity, and heat resistance.

4. Conclusion

Based on its review of the materials submitted by Dow, and in consultation with its expert, the Commission has concluded that CEF: (1) Has the same general chemical composition as an established generic fiber category (olefin); (2) has distinctive properties of importance to the general public as a result of a new method of manufacture or substantially differentiated physical characteristics, such as fiber structure (e.g., elasticity and heat resistance); and (3) that its distinctive feature(s) make the fiber suitable for uses for which other fibers under the established olefin generic name would not be suited, or would be significantly less well suited. Consequently, the Commission has determined that there are sufficient differences between CEF and conventional olefins to merit a new subclass designation. Therefore, the Commission is amending rule 7(m) to adopt and define the generic subclass name "lastol," and to allow use of the name "lastol" as an alternative to the generic name "olefin" for that subclass of fiber. Other companies that

⁶ In lamellae form, the polymer chains are folded in the crystalline or ordered regions.

⁷ In fringed micelle form, the polymer chains are extended and parallel to each other in the crystalline regions.

⁸ CEF's cross-linked polymer network structure also allows CEF to maintain its integrity in solvents that typically dissolve conventional olefins.

⁵ Interpolymer refers to polymers prepared by the polymerization of at least two different types of monomers, typically ethylene and octene.

manufacture fibers satisfying the definition also may use the subclass name in making required fiber content disclosures on labels.

The Commission has decided to simplify slightly the definition of "lastol" that Dow proposed and the Commission published for comment. The definition the Commission is adopting, however, is consistent with the definition, as proposed, as well as with the definition of "olefin" in rule 7(m). The new definition of "lastol" defines the fiber generically in terms of its chemical composition, and identifies its physical elasticity and heat resistance characteristics. In addition, the Commission is reducing the minimum percentage by weight of ethylene and other olefin unit constituting the polymer in the final definition of "lastol" from 99 percent, as proposed, to 95 percent to account for a small percentage of inorganic molecules in the fiber that, according to Dow, are not included in the polymer.

Accordingly, for the reasons discussed above, the Commission amends rule 7(m) of the Textile Rules by adding the following sentence at the end:

Where the fiber-forming substance is a cross-linked synthetic polymer, with low but significant crystallinity, composed of at least 95 percent by weight of ethylene and at least one other olefin unit, and the fiber is substantially elastic and heat resistant, the term *lastol* may be used as a generic description of the fiber.

III. Effective Date

The Commission is making the amendments effective today, January 27, 2003, 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.

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 as an alternative to an existing generic name for that defined subclass of fiber, 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. 67 FR 36551, at 36554 (May 24, 2002).

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 part 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 (m) is amended by adding a sentence at the end, to read as follows:

§ 303.7 Generic names and definitions for manufactured fibers.

* * * * *

(m) * * * Where the fiber-forming substance is a cross-linked synthetic polymer, with low but significant crystallinity, composed of at least 95 percent by weight of ethylene and at least one other olefin unit, and the fiber is substantially elastic and heat resistant, the term *lastol* may be used as a generic description of the fiber.

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By direction of the Commission.
Donald S. Clark,
Secretary.
[FR Doc. 03-1739 Filed 1-24-03; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lincomycin Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for oral use of lincomycin soluble powder to make medicated drinking water for administration to swine for the treatment of swine dysentery or to broiler chickens for the control of necrotic enteritis.

DATES: This rule is effective January 27, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64506-0457, filed ANADA 200-303 for Lincomycin Hydrochloride Soluble Powder. The application provides for oral use of lincomycin soluble powder to make medicated drinking water for administration to swine for the treatment of swine dysentery or to broiler chickens for the control of necrotic enteritis. Phoenix Scientific's Lincomycin Hydrochloride Soluble Powder is approved as a generic copy of Pharmacia & Upjohn's LINCOMIX Soluble Powder, approved under NADA 111-636. ANADA 200-303 is approved as of October 1, 2002, and the regulations are amended in 21 CFR 520.1263c to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and