§ 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 Section 126 of the Modernization Act also repealed section 502(d) of the act (21 U.S.C. 352(d)), which provided that a drug or device containing certain enumerated narcotic or hypnotic (habit-forming)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

the guidance, FDA believes that the habit-forming characteristics of a drug product should be adequately described in the ''Drug Abuse and Dependence'' section of the package insert and that further labeled warnings are not necessary.

IV. Implementation

A guidance for industry entitled ''Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997—Elimination of Certain Labeling Requirements'' (63 FR 39100, July 21, 1998) is available on the Internet at http://www.fda. gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm. The guidance indicates that, for the time periods and under the circumstances stated below, in the exercise of its enforcement discretion, FDA does not intend to object if a sponsor does not comply with the new labeling requirements of section 126 of the Modernization Act. The guidance advises that FDA does not intend to object if sponsors of certain currently approved products implement the new requirements of section 126 of the Modernization Act at the time of the next revision of their labels, or by February 19, 2003, whichever comes first, and report these minor changes in the next annual report. For pending (unapproved) full or abbreviated applications received by the agency prior to February 19, 1998, sponsors should comply with the new labeling requirements by the time of the next revision of their labels or by February 19, 2003, whichever comes first. The guidance also advises that full or abbreviated applications received by FDA after February 19, 1998, should provide labels and labeling in compliance with the new labeling requirements.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. As described in section IV of this document, the agency's guidance document explains that FDA will exercise its enforcement discretion in a manner that will permit companies to implement the required label changes at the time of the next revision of their labels, or by February 19, 2003, whichever comes first. Because almost all labels would typically be reprinted within this timeframe, this enforcement strategy will eliminate any significant costs that would otherwise be associated with the rule. As a result, the final rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options to minimize any significant impact of a rule on a substantial number of small entities. The agency certifies that the final rule would not have a significant impact on a substantial number of small entities because the lengthy implementation period will allow companies to make the necessary label changes during the normal course of business. Therefore, under the Regulatory Flexibility Act, no further analysis is required. Section 202(a) of the Unfunded Mandates Reform Act (Public Law 104–4) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year (adjusted annually for inflation). Because this rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an expenditure of $100 million or more in any one year, FDA is not required to perform a cost-benefit analysis under the Unfunded Mandates Reform Act.

VII. Paperwork Reduction Act of 1995

FDA concludes that this final rule does not require information collections subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (Public Law 104–13).

FDA is amending its labeling regulations by removing the requirement that prescription drugs be labeled with ''Caution: Federal law prohibits dispensing without prescription'' and adding a requirement that prescription drugs be labeled with ''Rx only'' or ''℞ only.'' This labeling statement is not subject to review by OMB because it is ''originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore does not constitute a ''collection of information'' under the PRA.

VIII. Executive Order 13132: Federalism

FDA has analyzed this final rule in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires Federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt existing State law. As defined in the Order, ''policies that have federalism implications'' refers to regulations, legislative comments or final legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the National Government and the States or on the distribution of power and responsibilities among the various levels of government.

This final rule revises FDA labeling regulations as required by the Modernization Act. Because enforcement of these labeling provisions is a Federal responsibility, there should be little, if any, impact from this rule on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. In addition, FDA does not believe that this final rule preempts any existing State law.

Accordingly, FDA has determined that this final rule does not contain policies that have federalism implications.

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 250

Drugs.

21 CFR Parts 290 and 329

Drugs, Labeling.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 341

Labeling, Over-the-counter drugs.

21 CFR Part 361

Medical research, Prescription drugs, Radiation protection.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and the Food and Drug Administration Modernization Act, and under authority delegated to the Commissioner of Food and Drugs, chapter I of Title 21 is amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 10.50 [Amended]

2. Section 10.50 *Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing* is amended by removing and reserving paragraph (c)(7).

PART 201—LABELING

3. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

§ 201.10 [Amended]

4. Section 201.10 *Drugs; statement of ingredients* is amended in paragraph (a) by removing the phrase ''as 'Warning—May be habit forming' ''.

5. Section 201.16 is revised to read as follows:

§ 201.16 Drugs; Spanish-language version of certain required statements.

An increasing number of medications restricted to prescription use only are being labeled solely in Spanish for distribution in the Commonwealth of Puerto Rico where Spanish is the predominant language. Such labeling is authorized under § 201.15(c). One required warning, the wording of which is fixed by law in the English language, could be translated in various ways, from literal translation to loose interpretation. The statutory nature of this warning requires that the translation convey the meaning properly to avoid confusion and dilution of the purpose of the warning. Section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act requires, at a minimum, that the label bear the statement ''Rx only.'' The Spanish-language version of this must be ''Solamente Rx''.

§ 201.100 [Amended]

6. Section 201.100 *Prescription drugs for human use* is amended in paragraph (b)(1) by removing the phrase '' 'Caution: Federal law prohibits dispensing without prescription' '' and by adding in its place the phrase '' 'Rx only' ''.

§ 201.120 [Amended]

7. Section 201.120 *Prescription chemicals and other prescription components* is amended in paragraph (b)(2) by removing the phrase '' 'Caution: Federal law prohibits dispensing without prescription' '' and by adding in its place the phrase '' 'Rx only' ''.

§ 201.122 [Amended]

8. Section 201.122 *Drugs for processing, repacking, or manufacturing* is amended in the first sentence of the introductory text by removing the phrase '' 'Caution: Federal law prohibits dispensing without prescription' '' and by adding in its place the phrase '' 'Rx only' ''.

§ 201.306 [Amended]

9. Section 201.306 *Potassium salt preparations intended for oral ingestion by man* is amended in paragraph (b)(1) by removing the word ''caution''.

PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

10. The authority citation for 21 CFR part 250 continues to read as follows:

Authority: 21 U.S.C. 321, 336, 342, 352, 353, 355, 361(a), 362(a) and (c), 371, 375(b).

§ 250.100 [Amended]

11. Section 250.100 *Amyl nitrate inhalant as a prescription drug for human use* is amended in paragraph (b) by removing the phrase ''legend 'Caution: Federal law prohibits dispensing without prescription.' '' and by adding in its place the phrase ''statement 'Rx only.' ''.

§ 250.101 [Amended]

12. Section 250.101 *Amphetamine and methamphetamine inhalers regarded as prescription drugs* is amended in paragraph (b) by removing the phrase ''legend 'Caution: Federal law prohibits dispensing without prescription.' '' and by adding in its place the phrase ''statement 'Rx only.' ''.

§ 250.105 [Amended]

13. Section 250.105 *Gelsemium-containing preparations regarded as prescription drugs* is amended in the last sentence by removing the phrase '' 'Caution: Federal law prohibits dispensing without prescription.' '' and by adding in its place the phrase '' 'Rx only.' ''.

§ 250.108 [Amended]

14. Section 250.108 *Potassium permanganate preparations as prescription drugs* is amended in paragraph (c)(1) by removing the phrase ''legend, 'Caution: Federal law prohibits dispensing without prescription.' '' and by adding in its place the phrase ''statement 'Rx only.' '' and in paragraph (c)(2) by removing the phrase '', 'Caution: Federal law prohibits dispensing without prescription.' '' and by adding in its place the phrase '' 'Rx only.' ''.

§ 250.201 [Amended]

15. Section 250.201 *Preparations for the treatment of pernicious anemia* is amended in paragraph (d) by removing the phrase ''legend 'Caution—Federal law prohibits dispensing without prescription.' '' and by adding in its place the phrase ''statement 'Rx only.' ''.

§ 250.250 [Amended]

16. Section 250.250 *Hexachlorophene, as a component of drug and cosmetic products* is amended in the last sentence of paragraph (c)(1) by removing the phrase ''legend 'Caution: Federal law prohibits dispensing without a prescription,' '' and by adding in its place the phrase ''statement 'Rx only,' '' and in paragraph (c)(4)(i) by removing the phrase ''prescription legend'' and by adding in its place the phrase ''statement 'Rx only' ''.

PART 290—CONTROLLED DRUGS

17. The authority citation for 21 CFR part 290 continues to read as follows:

Authority: 21 U.S.C. 352, 353, 355, 371.

18. Section 290.1 is added to subpart A to read as follows:

§ 290.1 Controlled substances.

Any drug that is a controlled substance listed in schedule II, III, IV, or V of the Federal Controlled Substances Act or implementing regulations must be dispensed by prescription only as required by section 503(b)(1) of the

Federal Food, Drug, and Cosmetic Act unless specifically exempted in § 290.2.

19. Section 290.2 is added to subpart A to read as follows:

§ 290.2 Exemption from prescription requirements.

The prescription-dispensing requirements of section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act are not necessary for the protection of the public health with respect to a compound, mixture, or preparation containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams that also includes one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by codeine alone.

PART 310—NEW DRUGS

20. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

§ 310.103 [Amended]

21. Section 310.103 *New drug substances intended for hypersensitivity testing* is amended in paragraph (a)(3)(i) by removing the phrase '' 'Caution: Federal law prohibits dispensing without a prescription' '' and by adding in its place the phrase '' 'Rx only' ''.

PART 329—HABIT FORMING DRUGS

22. Part 329 is removed.

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

23. The authority citation for 21 CFR part 341 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

§ 341.14 [Amended]

24. Section 341.14 *Antitussive active ingredients* is amended in paragraph (a)(2) by removing ''§§ 329.20(a) and 341.40'' and by adding in its place ''§ 290.2''.

PART 361—PRESCRIPTION DRUGS FOR HUMAN USE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED: DRUGS USED IN RESEARCH

25. The authority citation for 21 CFR part 361 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 371; 42 U.S.C. 262.

§ 361.1 [Amended]

26. Section 361.1 *Radioactive drugs for certain research uses* is amended in paragraph (f)(1) by removing the phrase '' 'Caution: Federal law prohibits dispensing without prescription' '' and by adding in its place the phrase '' 'Rx only' ''.

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

27. The authority citation for 21 CFR part 369 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371.

§ 369.22 [Removed]

28. Section 369.22 is removed.

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

29. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

30. Section 606.121 is amended by revising paragraph (c)(8)(i) to read as follows:

§ 606.121 Container label.

* * * * *

(c) * * *

(8) * * *

(i) ''Rx only.''

* * * * *

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

31. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 610.60 [Amended]

32. Section 610.60 *Container label* is amended in paragraph (a)(6) by removing the phrase '' 'Caution: Federal law prohibits dispensing without prescription,' '' and by adding in its place the phrase '' 'Rx only' ''.

§ 610.61 [Amended]

33. Section 610.61 *Package label* is amended in paragraph (s) by removing the phrase '' 'Caution: Federal law prohibits dispensing without prescription,' '' and by adding in its place the phrase '' 'Rx only' ''.

Dated: January 28, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–2548 Filed 1–31–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8982]

RIN 1545–AY19

Definition of Disqualified Person

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations narrowing the definition of the term disqualified person for section 1031 like-kind exchanges. The amendments in the regulations are in response to recent changes in the federal banking law, especially the repeal of section 20 of the Banking Act of 1933 (commonly referred to as the Glass-Steagall Act). The regulations will affect the eligibility of certain persons to serve as escrow holders of qualified escrow accounts, trustees of qualified trusts, and qualified intermediaries.

DATES: *Effective Date:* These regulations are effective February 1, 2002.

Dates of Applicability: These regulations apply to transfers of property made by a taxpayer on or after January 17, 2001.

FOR FURTHER INFORMATION CONTACT: Brendan O'Hara, (202) 622–4920 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR Part 1) under § 1.1031(k)–1. On January 17, 2001, the IRS and Treasury Department published in the **Federal Register** a notice of proposed rulemaking under section 1031 (66 FR 3924). The notice proposed to amend § 1.1031(k)–1(k) by narrowing the definition of the term *disqualified person.* Comments responding to the notice were received, and a public hearing was held on June 5, 2001. After considering the comments received in response to the notice of proposed rulemaking and the statements made at the public hearing, the proposed regulations are adopted as revised by this Treasury decision. The comments and revisions are discussed below.