Guides. Based on this information, the Commission determined that it was in the public interest to offer guidance to the industry thereby promoting a higher level of compliance with the laws administered by the Commission by adopting the Guides. The Guides are voluntary guidelines containing interpretations of acts or practices that the Commission has issued to assist members of the industry in complying with Section 5 of the FTC Act.

The Furniture Guides generally advise members of the industry to make affirmative disclosures for the benefit of consumers to ensure that the prospective purchaser is not misled into thinking that the product is different from that which is actually offered, because of the appearance, description, depictions or representations made about the product, in advertising, labeling or other promotional materials. The Guides also advise that advertisers making representations concerning (a) tests made on products, or (b) the performance characteristics of upholstery fabrics do in fact have a ''reasonable basis'' for such representations. Further, the guides also inform advertisers that the Commission may require documentation from them to substantiate their representations concerning the product. The Guides also provide several definitions for the industry, including definitions regarding certain types of wood. In summary, the Guides for the Household Furniture Industry, 16 CFR Part 250, advise members of the industry to:

(1) Make affirmative disclosures of material facts concerning merchandise, which if known to a purchaser, would influence his or her decision to purchase the merchandise:

(2) Attach an accurate tag or label in a prominent location on each product;

(3) Describe wood, wood imitations and color used in or on furniture only with qualified wood names or generally accepted wood names. The description shall not be deceptive;

(4) Identify certain woods as ''walnut'', ''mahogany'' and ''mapel'' only if such woods are derived from specified species;

(5) Refrain from making representations or misleading inferences about a product being made of leather, when in fact it is not;

(6) Refrain from making false or misleading representations concerning outer coverings of furniture or furniture stuffing;

(7) Accurately describe the origin of furniture, whether domestic or foreign; and whether the furniture is actually new, being made of parts and materials that were entirely unused;

(8) Refrain from describing as ''floor sample'' furniture that has been rented, repossessed or ''traded-in'';

(9) Refrain from using deceptive trademarks or claiming to be a manufacturer or wholesaler when in fact they are not; and

(10) Look to the applicable guides and rules for further guidance on guarantees, pricing and advertising.

II. Regulatory Review Program

The Commission has determined to review all current Commission rules and guides periodically. These reviews seek information about the costs and benefits of the Commission's rules and guides and their regulatory and economic impact. The information obtained assists the Commission in identifying rules and guides that warrant modification or rescission. Therefore, the Commission solicits comments on, among other things, the economic impact of and the continuing need for the Household Furniture Industry Guides; possible conflict between the Guides and state, local or other federal laws; and the effect on the Guides of any technological, economic, or other industry changes.

III. Request for Comments

The Commission solicits written public comments on the following questions:

1. Is there a continuing need for the Household Furniture Guides?

(a) What benefits have the Guides provided to purchasers of the products or services affected by the Guides?

(b) Have the Guides imposed costs on purchasers?

2. What changes, if any, should be made to the Guides to increase the benefits of the Guides to purchasers?

(a) How would these changes affect the costs the Guides impose on companies subject to their requirements?

3. What significant burdens or costs, including costs of adherence, have the Guides imposed on companies subject to their requiements?

(a) Have the Guides provided benefits to such companies?

4. What changes, if any, should be made to the Guides to reduce the burdens or costs imposed on companies subject to their requirements?

(a) How would these changes affect the benefits provided by the Guides?

5. Do the Guides overlap or conflict with other federal, state, or local laws or regulations?

6. Since the Guides were issued, what effects, if any, have changes in the relevant technology or economic conditions had on the Guides?

7. What effect, if any, has the use of modern technology such as the Internet and E-mail had on the Guides?

(a) How has the use of modern technology such as the Internet and E-mail affected the rights of consumers and the responsibilities of sellers?

8. Are there any abuses in the marketing of furniture products that are not addressed by the Guides?

(a) What mechanisms (*e.g.,* consumer education, self-regulation, amendment or rescission of the Guides) should be explored to deal with any marketing abuses that may exist?

9. What significant burdens or costs, including costs of adherence, have the Guides imposed on small companies subject to their requirements?

(a) How do these burdens or costs differ from those imposed on larger companies subject to the requirements of the Guides?

10. To what extent are the burdens or costs that the Guides impose on small companies similar to those that small companies would incur under standard and prudent business practices?

11. What changes, if any, should be made to the Guides to reduce the burdens or cost imposed on small companies?

(a) How would these changes affect the benefits of the Guides?

(b) Would such changes adversely affect the competitive position of larger companies?

List of Subjects in 16 CFR Part 250

Forest and forest products, Furniture industry, Trade practices.

Authority: 15 U.S.C. 41–58

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 00–8770 Filed 4–7–00; 8:45 am]

BILLING CODE 6750–01–M

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to

amend its regulations to require the labels of prescription drugs to bear the statement ''only'' instead of the statement ''Caution: Federal law prohibits dispensing without prescription'' and to remove the requirement that certain habit-forming drugs bear the statement ''Warning—May be habit forming.'' The agency is also proposing to add a new section to the regulations to make clear that these habit-forming drugs must be dispensed by prescription only. The agency is taking this action to implement changes made by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments by June 26, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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. The Modernization Act

On November 21, 1997, President Clinton signed into law the Modernization Act (Public Law 105–115). 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 ''Rxonly'' instead of the statement ''Caution: Federal law prohibits dispensing without prescription.'' The new label statement may be printed as either ''Rx only'' or ''Rx only.''[1] 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.''

II. Description of the Proposed Rule

The proposed rule would amend 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 proposed rule would amend 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 proposed rule would remove part 329. Part 329 was issued under repealed section 502(d) of the act. Section 329.1 designates as habit-forming certain derivatives of the habit-forming substances listed in section 502(d) of the act. Section 329.10 elaborates on the labeling requirement of section 502(d) of the act.

Section 329.20 exempts certain habit-forming drugs from the prescription-dispensing requirements of the act. This section has not been substantively revised in more than 30 years. It is now out of date. Except as discussed elsewhere in this section, none of the drug ingredients listed as exempt in § 329.20 are currently marketed over-the-counter (OTC) or have any legal basis to be marketed OTC.

The proposed rule would amend 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 503(b)(1) provides that a drug that ''because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use,'' or a drug which ''is limited by an approved application under section 505 of the act to use under the professional supervision of a practitioner licensed by law to administer such drug,'' shall be dispensed only upon a prescription of a practitioner licensed by law to administer such drug. Generally, a drug that meets the criteria for control under Schedule II, III, IV, or V of the CSA (see 21 U.S.C. 812) would also meet the standard for prescription dispensing under section 503(b)(1) of the act. Drugs included in Schedule I of the CSA cannot be lawfully marketed in the United States.

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. Small amounts of codeine in combination with other nonnarcotic active medicinal ingredients, for example, cough syrup with codeine, may be marketed OTC under a final monograph for cold and cough products. (See § 341.14 (21 CFR 341.14)). For the reason stated above, no other exemptions are warranted at this time for the other narcotic drugs listed in § 329.20(a). Also, an exemption under § 290.2 is not needed for the chlorobutanol preparations described in § 329.20 because chlorobutanol is not a scheduled substance under the CSA. The epinephrine product described in § 329.20(c) cannot be lawfully marketed at this time.

The proposed rule would also revise § 341.14 to refer to the exemption at § 290.2, rather than § 329.20 which is being removed.

III. 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 in this section, 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 a sponsor of a currently approved product implements the new requirements of section 126 of the Modernization Act at the time of the next revision of its labels, or by February 19, 2003, whichever comes first, and reports 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

[1] 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.

compliance with the new labeling requirements.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) through (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.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. 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 proposed rule is not a significant action as defined by the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options to minimize any significant impact on a substantial number of small entities. The agency certifies that the proposed rule would not have a significant impact on a substantial number of small entities because the 5-year 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. The Unfunded Mandates Reform Act (in section 202) 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.

VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Public Law 104–13) is not required. The revised labeling information is supplied by the Modernization Act (changing ''Caution: Federal law prohibits dispensing without prescription'' to ''℞ only'' or ''℞ only''). According to 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not considered a collection of information.

VII. Request for Comments

Interested persons may, on or before June 26, 2000, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Proposed Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 60 days after publication of the final rule. For information on implementation, see the discussion in section III of this document.

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, and the Food and Drug Administration Modernization Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of Title 21 be amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 is revised 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 ''SoAE1lamente 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 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 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 introductory text, first sentence, by removing the phrase '' 'Caution: Federal law prohibits dispensing without prescription' '' and 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 nitrite 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 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 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 by removing the phrase '' 'Caution: Federal law prohibits dispensing without prescription.' '' from the last sentence and 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 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 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 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 adding in its place the phrase ''statement 'Rx only,' '' and in paragraph (c)(4)(i) by removing the phrase ''prescription legend'' and 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 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 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 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 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 adding in its place the phrase '' 'Rx only' ''.

Dated: March 31, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–8737 Filed 4–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Defense Commissary Agency

32 CFR Part 327

Defense Commissary Agency Privacy Act Program

AGENCY: Defense Commissary Agency, DOD

ACTION: Proposed rule.

SUMMARY: This proposed rule establishes the Defense Commissary Agency Privacy Act Program. This rule establishes policies and procedures for implementing the DeCA Privacy Program, and delegates authorities and assigns responsibilities for the administration of the DeCA Privacy Program.

DATES: Comments must be received by June 9, 2000, to be considered by the agency.

ADDRESSES: Defense Commissary Agency, 1300 E. Avenue, Fort Lee, VA 23801-1800.

FOR FURTHER INFORMATION CONTACT: Ms. Carole Marsh at (804) 734-8841.

SUPPLEMENTARY INFORMATION: Executive Order 12866. It has been determined that this Privacy Act rule for the Department of Defense does not constitute 'significant regulatory action'. Analysis of the rule indicates that it does not have an annual effect on the economy of $100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Regulatory Flexibility Act. It has been determined that this Privacy Act rule for the Department of Defense does not have significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Paperwork Reduction Act. It has been determined that this Privacy Act rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act of 1974.

List of subjects in CFR 32 CFR Part 327

Privacy.

Accordingly, Title 32 of the CFR is proposed to be amended in Chapter I, subchapter O, by adding part 327 to read as follows:

PART 327 - DEFENSE COMMISSARY AGENCY PRIVACY ACT PROGRAM

Sec.

Authority: Pub. L. 93-579, 88 Stat 1896 (5 U.S.C. 552a).

§ 327.1 Purpose.

This part implements the basic policies and procedures for the implementation of the Privacy Act of 1974, as amended (5 U.S.C. 552a); OMB Circular A-130 [1]; and 32 CFR part 310; and to promote uniformity in the DeCA Privacy Act Program.

§ 327.2 Applicability.

This part applies to Headquarters, Field Operating Activities (FOA), Regions, Zones, Central Distribution Centers (CDC), Commissaries of DeCA, and contractors during the performance of a contract with DeCA. All personnel are expected to comply with the procedures established herein.

§ 327.3 Responsibilities.

(a) *The Director, DeCA:*

(1) Supervises the execution of the Privacy Act and this part within the DeCA, and serves as the DeCA Privacy Act Appeal Authority.

[1] Copies may be obtained: http://www.whitehouse.gov/OMB/circulars