

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 341

[Docket No. 95N-0205]

RIN 0905-AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Monograph for OTC Bronchodilator Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the final monograph for over-the-counter (OTC) bronchodilator drug products to remove the ingredients ephedrine, ephedrine hydrochloride, ephedrine sulfate, and racedephedrine hydrochloride and to classify these ingredients as not generally recognized as safe and effective for OTC use. This action is being taken in response to a request from the U.S. Department of Justice, Drug Enforcement Administration (DEA) to restrict OTC availability of ephedrine because of its illicit use as the primary precursor utilized in the synthesis of the controlled substances methamphetamine and methcathinone. This action is also based on new information that shows that the misuse and abuse of OTC ephedrine drug products has the potential for causing harm and on comments made by FDA's Pulmonary-Allergy Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee on November 14, 1994. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments or objections by August 28, 1995; written comments on the agency's economic impact determination by August 28, 1995. FDA is proposing that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

ADDRESSES: Submit written comments or objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-810), Food and Drug Administration, 5600

Fishers Lane, Rockville, MD 20857, 301-594-5000.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 9, 1976 (41 FR 38312), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products, together with the recommendations of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. The Panel recommended that ephedrine preparations be Category I (generally recognized as safe and effective) for OTC bronchodilator use (41 FR 38312 at 38370 and 38371, September 9, 1976). The agency concurred with the Panel in the bronchodilator tentative final monograph (47 FR 47520 at 47527, October 26, 1982) and included ephedrine preparations in the final monograph for OTC bronchodilator drug products (51 FR 35326 at 35339, October 2, 1986).

II. Recent Developments

Since publication of the final monograph for OTC bronchodilator drug products, the agency's views about OTC ephedrine-containing bronchodilator drug products have changed for several reasons: (1) A large-scale diversion of OTC ephedrine-containing drug products to illicit use in the manufacture of the controlled substances methamphetamine and methcathinone, (2) new information that ephedrine may be unsafe for OTC use and has the potential for causing harm as a result of misuse and abuse, due to widespread and easy availability as an OTC drug, and (3) the consensus of FDA's Pulmonary-Allergy Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee (the Committee) on November 14, 1994, that the use of oral ephedrine drug products as an OTC bronchodilator to relieve the symptoms of asthma can no longer be justified when the drug's potential for illicit use and misuse is considered.

III. Illicit Use of OTC Ephedrine Drug Products

FDA has received correspondence and inquiries from consumers, U.S. Senators, DEA, and others (Ref. 1) concerning the need for additional

controls on the distribution of OTC ephedrine-containing drug products. The "Domestic Chemical Diversion Control Act of 1993, Pub. L. 103-200" was signed into law on December 17, 1993, to control the diversion of certain chemicals (e.g., ephedrine) used in the illicit production of controlled substances such as methcathinone and methamphetamine. The law became effective on April 16, 1994, and removed the exemption from the definition of a "regulated transaction" that had existed for single entity ephedrine drug products legally marketed under the Federal Food, Drug, and Cosmetic Act (the act). Thus, drugs that were previously marketed lawfully under the act are no longer exempt from chemical precursor controls. The new law was intended to close this loophole and help eliminate the availability of ephedrine as a raw material source in the clandestine synthesis of methamphetamine and methcathinone.

In the **Federal Register** of October 11, 1994 (59 FR 51365), DEA issued a final rule eliminating the threshold for ephedrine and subjecting all transactions involving bulk ephedrine and single entity ephedrine drug products to the applicable provisions of the Controlled Substances Act (21 U.S.C. 801). The final rule eliminated the threshold (an amount of a listed chemical that determines if a transaction such as receipt or sale of the chemical is a regulated transaction under part 1310 (21 CFR part 1310)) for single entity ephedrine drug products. The final rule established that all transactions involving ephedrine, regardless of size, are subject to recordkeeping and reporting requirements set forth in part 1310 and the notification provisions of part 1310 (21 CFR part 1313). However, the final rule did not apply to combination drug products containing ephedrine.

At the Committee meeting on November 14, 1994, the Committees discussed OTC bronchodilator drug products. DEA had submitted a comment (Ref. 2) to the Committee expressing its concern that, although the recent legislation and proposed regulations (59 FR 12562, March 17, 1994) (now final regulations (59 FR 51365)) adequately address the ability to control single ingredient ephedrine products, DEA is aware that laboratories may turn to combination drug products containing ephedrine and guaifenesin that would be exempt from the final rule.

The comment stated that the illicit use of OTC ephedrine drug products is contributing to a serious public health problem that is an extremely critical

issue requiring further action at the Federal level. The comment added that the OTC marketing status and broad distribution of these products is hindering efforts to prevent this illicit use of ephedrine and urged the Committees to restrict the OTC availability of this ingredient.

The agency has also received comments from county, State, and Federal Government organizations; pharmacists' associations; and consumers who object to the continued marketing of OTC ephedrine drug products because some manufacturers are promoting these products for misuse as stimulant, weight control, and muscle enhancement products (Ref. 3). The comments contended that this promotion has resulted in extensive and extremely dangerous misuse and abuse of such products, particularly in teenaged children.

IV. Misuse and Abuse of OTC Ephedrine Drug Products

The agency has received a number of reports (Ref. 4) of young people abusing OTC ephedrine drug products. In one case, nine junior high school students took three to eight ephedrine 25 milligram (mg) tablets for added energy and experienced rapid heart beats. One female who took eight tablets had 200 heart beats per minute 2 hours after taking the tablets. The student was able to purchase the ephedrine tablets from a product display at a local convenience store without being questioned about the reason for its use. Another report (Ref. 5) indicated that three 15-year-old girls had consumed 24 to 33 tablets of ephedrine-containing OTC drugs for "kicks."

The agency is aware of numerous other reports involving young people who have overdosed by using OTC ephedrine products promoted as a stimulant or for weight control, or by using such products for recreational purposes in high doses and on a regular basis. One report (Ref. 5) involved a 17-year-old male who died after ingesting a toxic or lethal amount of ephedrine. The youth apparently took the ephedrine to increase alertness, strength, and physical stamina. In another case (Ref. 4), a 21-year-old female developed respiratory problems (trouble breathing) after taking three to four 25 mg ephedrine tablets, purchased OTC, every other hour (and then every hour) over an 8-hour period and consuming alcoholic beverages. Hospitalization resulted from this recreational use of ephedrine.

In another case (Ref. 4), a 22-year-old female took OTC ephedrine tablets because her friends had told her they

would act as "uppers." The woman's job required her to work long hours, and she felt she needed a chemical pick-up to get through the day. She presented to a hospital emergency room with headache, nausea, anxiety, and blood pressure of 170/110 millimeters mercury. She was treated, with no permanent adverse effects.

FDA's Spontaneous Reporting System also contains a number of reports of ephedrine misuse and abuse (Ref. 4), some of which have resulted in death due to an overdose of ephedrine. In one case, a 52-year-old male took 10 to 15 ephedrine tablets (believed to be 50 mg) over the previous 24 hours. In another case, a 24-year-old male who died of an overdose had a blood level of ephedrine over 30 times the usual therapeutic range. In another overdose case, the reporting pharmacist commented that "ephedrine is becoming a drug for abuse—would recommend to withdraw OTC status." In another case, the reporting hospital pharmacist noted that the ephedrine overdose (in a 19-year-old female) was the second incident observed this year for these ephedrine/caffeine products sold at convenience markets and "not FDA regulated."

Interested consumers and state regulatory officials (e.g., health departments, boards of pharmacy) have expressed concern about OTC ephedrine drug products being sold under brand names that reflect a use other than as a bronchodilator (e.g., use as a stimulant or for weight control); about products being readily available at convenience stores, truck stops, gas stations, and mini-marts with little, or no, restriction on their sale; and about products being purchased and used by children and adolescents, on an ever increasing basis, with a continuing increase in the number of reported adverse events.

One director of an addictions program informed FDA (Ref. 6) that his locality (in Indiana) is experiencing a surge of adverse responses or reactions to the use of OTC ephedrine being abused for its stimulant effect. He reported that a number of people abusing ephedrine have demonstrated stimulant dependence characterized by compulsion, obsession, or preoccupation, and that ephedrine abuse has induced or worsened mental disorders such as depressive anxiety and different thought disorders. He stated that people are obtaining the drug OTC as ephedrine (not in combination with other drugs) under different brand names, some of which are advertised as an "energizer." He mentioned that the age group abusing ephedrine ranges from teenagers to people who are in their 40's.

A nurse reported her daughter's adverse experience with an OTC ephedrine product (Ref. 4) and mentioned that within the last year the child's pediatrician had treated several adolescents who had overdosed on ephedrine. The nurse added that many emergency room physicians are seeing behavior similar to schizophrenia occurring in young adults as a result of ephedrine obtained OTC. The nurse questioned why this drug was readily purchasable by unsuspecting teenagers.

The agency concludes that these reports show that OTC ephedrine drug products are marketed in ways that are misleading, that promote misuse and abuse, and that can be dangerous. The agency believes that these reports represent only a small percentage of the actual number of adverse events that have occurred and that ephedrine misuse and abuse are a widespread problem in the United States.

According to one source (Ref. 7), at least 14 states have placed additional controls and restrictions on ephedrine to address the abuse problem. These controls include, in at least five states (Florida, Idaho, New Mexico, Oregon, and Washington), switching the products to prescription only status. In Michigan, possession of more than 4 grams of ephedrine requires a prescription. Six states (Arizona, Missouri, Nevada, Ohio, Oklahoma, and Wisconsin) have scheduled ephedrine as a controlled substance. The agency is aware that Kentucky, Massachusetts, and Virginia have introduced bills to tighten ephedrine controls and that other states are also considering similar actions.

The agency concludes that the misuse and abuse of OTC ephedrine drug products have the potential for causing harm as shown by the many reports submitted to the agency. FDA has determined that action is needed to eliminate this misuse/abuse potential. FDA's proposed action, when finalized, will eliminate the need for future action by individual states.

V. Advisory Committee Comments

At a meeting of FDA's Pulmonary-Allergy Drugs Advisory Committee and Nonprescription Drugs Advisory Committee (the Committee) held on November 14, 1994, the Committee members heard presentations from private citizens and state officials concerning the misuse and abuse of OTC ephedrine drug products (Ref. 8). The Committee members expressed concern about the reports of abuse and illicit diversion of ephedrine. One Committee member mentioned that removal of ephedrine from the OTC

marketplace by FDA or DEA regulatory action would cause no harm and, indeed, would do some amount of good. Although the Committee did not hear from manufacturers of OTC ephedrine drug products and was not asked the specific question whether these products should be removed from the OTC market, there was a consensus that the benefit of OTC ephedrine does not justify its continued use as an OTC bronchodilator active ingredient when the potential for illicit use and misuse is considered (Ref. 9).

FDA received comments from manufacturers in response to the notice for the Committee meeting (59 FR 34847, July 7, 1994). Two manufacturers opposed the marketing of any OTC bronchodilator drug product (Ref. 10). One manufacturer submitted a "Profile of Asthma Sufferers and Users of Nonprescription Epinephrine (Mist) and Ephedrine Combination (Tablets)" in support of its position these drug products remain available OTC (Ref. 11). Another manufacturer supported the continued marketing of legitimate OTC ephedrine-containing bronchodilator drug products (Ref. 12). This manufacturer briefly discussed the abuse potential for single ingredient ephedrine-containing products, particularly those that are deliberately labeled to imply nonmonographed usage. The manufacturer stated that the extent of any abuse is unclear and potentially exaggerated by a small number of highly publicized abuse instances. The comment noted that a number of states have enacted legislation to discourage abuse, in response to this situation. The comment mentioned that most states have generally made provisions to ensure continued OTC availability of legitimate combination asthma products, such as its product containing ephedrine sulfate and guaifenesin, an expectorant.

The agency has considered the manufacturers' views in developing this proposal. As discussed above, the agency believes that the misuse/abuse problem is widespread and much broader than one manufacturer suggested. Continued OTC availability of combination products containing ephedrine and guaifenesin would not alleviate this problem. Large quantities of guaifenesin are generally safe, and the combination product would not stop people from taking large amounts for the effects of the ephedrine. Further, DEA has informed FDA that it is aware that ephedrine can readily be isolated from such combinations for illicit manufacture (Ref. 13). Accordingly, FDA concludes that the best resolution for this misuse/abuse problem is for

ephedrine, singly or in combination products, not to be available OTC.

VI. References

The following references are on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

- (1) Correspondence in OTC Vol. 04BPEA, Docket No. 95N-0205, Dockets Management Branch.
- (2) Comment No. C6, Docket No. 94N-0232, Dockets Management Branch.
- (3) Comments No. C5, C6, C10, C11, C12, C17, C19, C20, APE8, APE10, APE13, and LET142, Docket No. 94N-0232, Dockets Management Branch.
- (4) Adverse reaction reports in OTC Vol. 04BPEA, Docket No. 95N-0205, Dockets Management Branch.
- (5) Comment No. C10, Docket No. 94N-0232, Dockets Management Branch.
- (6) Letter from B. B. Rohrer, The Addictions Program, to FDA, dated June 24, 1993, in OTC Vol. 04BPEA, Docket No. 95N-0205, Dockets Management Branch.
- (7) National Association of Boards of Pharmacy Foundation, Inc. Newsletter, October 1994, pp. 2-3, in OTC Vol. 04BPEA, Docket No. 95N-0205, Dockets Management Branch.
- (8) Transcript of a Joint Meeting of the Pulmonary-Allergy Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee, November 14, 1994, pp. 56-84, in OTC Vol. 04BPEA, Docket No. 95N-0205, Dockets Management Branch.
- (9) Transcript of a Joint Meeting of the Pulmonary-Allergy Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee, November 14, 1994, pp. 235, 236, 258, 259, 264, 265, 270, 271, and 272, in OTC Vol. 04BPEA, Docket No. 95N-0205, Dockets Management Branch.
- (10) Comments No. C8, APE1, and C11, Docket No. 94N-0232, Dockets Management Branch.
- (11) Comment No. LET144, Docket No. 94N-0232, Dockets Management Branch.
- (12) Comment No. C18, Docket No. 94N-0232, Dockets Management Branch.
- (13) Memorandum of a telephone conversation between D. Snyder, DEA, and G. Rachanow, FDA, dated April 20, 1994, in OTC Vol. 04BPEA, Docket No. 95N-0205, Dockets Management Branch.

VII. Summary of the Agency's Proposed Change

The agency is proposing that ephedrine, ephedrine hydrochloride, ephedrine sulfate, and racephedrine hydrochloride should no longer be included in the final monograph for OTC bronchodilator drug products based on their extensive use in illicit drug manufacture and their potential for causing harm as a result of misuse and abuse due to their widespread and easy availability as an OTC drug. This proposed amendment removes the ingredients ephedrine, ephedrine

hydrochloride, ephedrine sulfate, and racephedrine hydrochloride from the final monograph for OTC bronchodilator drug products (21 CFR part 341). It does not affect the monograph status of epinephrine-containing drug products when used in a hand-held rubber bulb nebulizer. Such products will remain in the final monograph for OTC bronchodilator drug products.

This proposal would remove all oral systemically acting bronchodilator drug products from the OTC market. Thus, the agency is proposing to amend § 341.16 of the final monograph for OTC bronchodilator drug products to remove §§ 341.16(a), (b), (c), and (f) for ephedrine ingredients and to redesignate § 341.16(d), (e), and (g) as § 341.16(a), (b), and (c), respectively. Also, the agency is proposing to amend § 341.76(c) to remove paragraph (5), to revise the heading for paragraph (6), and to redesignate paragraphs (6)(i), (6)(ii), and (6)(iii) as paragraphs (5)(i), (5)(ii), and (5)(iii), respectively. In addition, the agency is proposing to amend § 341.76(d) to remove paragraph (1), to redesignate paragraph (2) as paragraph (1), to revise the heading in new paragraph (1), and to reserve paragraph (2). The agency is also proposing to amend § 341.90 by removing paragraph (a) that pertains to ephedrine and redesignating paragraphs (b) through (q) as paragraphs (a) through (p), respectively. Furthermore, the agency is proposing to amend the list of ingredients that are not generally recognized as safe and effective for specified uses in § 310.545 (21 CFR 310.545) by adding new paragraphs (a)(6)(iv)(D) and (d)(27) for ephedrine preparations.

VIII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). 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. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory

options that would minimize any significant impact of a rule on small entities. This rule would eventually stop the marketing of OTC bronchodilator drug products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, or racebookedrine hydrochloride. The agency has determined that legitimate drug manufacturers have little or no interest in single ingredient OTC ephedrine drug products. However, some manufacturers may have an interest in combination drug products containing ephedrine.

The agency acknowledges that this proposed rule, if finalized, would have an impact on consumers who legitimately use OTC bronchodilator drug products containing ephedrine to relieve their bronchial asthma. They will no longer be able to purchase these products without a doctor's prescription. However, all OTC bronchodilator drug products must bear a label warning that states "Do not use this product unless a diagnosis of asthma has been made by a doctor." Therefore, it is presumed that legitimate users of these products have seen a doctor and are under a doctor's occasional care for the treatment of their asthma. These consumers will be able to obtain an ephedrine drug product upon a doctor's prescription if the doctor determines that ephedrine is the drug that should be used to treat the condition. These consumers will also be able to purchase OTC epinephrine for inhalation to treat their bronchial asthma without a doctor's prescription. At its November 14, 1994, meeting, the Committee recommended that epinephrine for inhalation remain available OTC for self-treatment of asthma under certain conditions. The agency has weighed the consequences of this proposed rule as it might adversely impact some legitimate users of these OTC ephedrine drug products. However, these consumers will have access to another drug without a prescription and could continue to obtain ephedrine products on a doctor's prescription. The agency has determined that as a result of the widespread misuse and abuse of OTC ephedrine drug products, especially by many young people and people up to in their 40's, that it is in the best interest of all consumers (especially parents) to remove from the OTC market ingredients that are used extensively in the manufacture of illicit drugs and that have widespread misuse and abuse with the potential to cause harm. Further, the agency is not aware of a widespread marketing of legitimate OTC bronchodilator drug products

containing ephedrine, although several manufacturers could be adversely affected by this proposed rule. Accordingly, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC bronchodilator drug products that contain ephedrine, ephedrine hydrochloride, ephedrine sulfate, or racebookedrine hydrochloride. Comments regarding the impact of this rulemaking on these drug products should be accompanied by appropriate documentation. A period of 30 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for development and submission of comments on this subject. Because of the existing serious public health problem identified by DEA and a number of states, and the many reports of misuse and abuse of OTC ephedrine drug products that FDA has received, the Commissioner has determined that there is good cause for a shortened comment period. FDA will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

IX. Environmental Impact

The agency has determined that under 21 CFR 25.24(c)(6) 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.

Interested persons may, on or before August 28, 1995, submit to the Dockets Management Branch (address above) written comments or objections regarding this proposal. Written comments on the agency's economic impact determination may be submitted on or before August 28, 1995. Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments and objections are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments and objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

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. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 310 and 341 be amended as follows:

PART 310—NEW DRUGS

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

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512-516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b-360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354-360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b-263n).

2. Section 310.545 is amended by adding new paragraphs (a)(6)(iv)(D) and (d)(27) and by revising paragraph (d) introductory text to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

- (a) * * *
 (6) * * *
 (iv) *Bronchodilator drug products.*
 * * *

(D) Approved as of August 28, 1995.
 Ephedrine
 Ephedrine hydrochloride
 Ephedrine sulfate
 Racephedrine hydrochloride
 * * * * *

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(27) of this section.
 * * * * *

(27) August 28, 1995, for products subject to paragraph (a)(6)(iv)(D) of this section.

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

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

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

§ 341.16 [Amended]

4. Section 341.16 Bronchodilator active ingredients is amended by removing paragraphs (a), (b), (c), and (f) and by redesignating paragraphs (d), (e), and (g) as paragraphs (a), (b), and (c), respectively.

5. Section 341.76 is amended by removing paragraph (c)(5); redesignating paragraph (c)(6) as paragraph (c)(5); and revising the heading for newly redesignated paragraph (c)(5); by removing paragraph (d)(1); by redesignating paragraph (d)(2) as

paragraph (d)(1); by reserving paragraph (d)(2); and by revising the heading in newly redesignated paragraph (d)(1) to read as follows:

§ 341.76 Labeling of bronchodilator drug products.

* * * * *

(c) * * *

(5) For products containing epinephrine, epinephrine bitartrate, or racepinephrine hydrochloride identified in § 341.16(a), (b), and (c). * * *

* * * * *

(d) * * *

(1) For products containing epinephrine, epinephrine bitartrate, or

racepinephrine hydrochloride identified in § 341.16(a), (b), and (c). * * *
(2) [Reserved]

* * * * *

§ 341.90 [Amended]

7. Section 341.90 *Professional labeling* is amended by removing paragraph (a) and redesignating paragraphs (b) through (q) as paragraphs (a) through (p), respectively.

Dated: July 5, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95-18448 Filed 7-26-95; 8:45 am]

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