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 racephedrine 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 racephedrine 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 ANTIASTHMATIC 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