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105TH CONGRESS
1ST SESSION

H. R. 2968

To require the Secretary of Health and Human Services to take no further action on proposed regulation relating to the use of chlorofluorocarbons in metered-dose inhalers.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 8, 1997

Mr. SMITH of New Jersey (for himself and Mr. STEARNS of Florida) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To require the Secretary of Health and Human Services to take no further action on proposed regulation relating to the use of chlorofluorocarbons in metered-dose inhalers.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. CHLOROFLUOROCARBONS IN METERED-DOSE INHALERS.

In complying with Title VI of the Clean Air Act, 42 U.S.C. 7671, and the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol), September 16, 1987, S. Treaty Doc. No. 10, 100th Cong.,

1st session, regarding chlorofluorocarbons (CFCs), any regulations under which the Secretary of Health and Human Services may remove essential use designations for the purpose of phasing out essential use allowances for drug products shall require the Secretary of Health and Human Services to certify to the Congress that alternatives to such inhalers are available that, for all populations of users of such inhalers, are comparable in terms of safety and effectiveness, therapeutic indications, dosage strength, cost, and retail availability.

SEC. 2. PROCESS FOR FURTHER RULEMAKING.

The Commissioner of the Food and Drug Administration shall withdraw the March 6, 1997 advance notice of proposed rulemaking concerning CFCs in metered-dose inhalers (MDIs) and shall issue another proposal only after the 10th Meeting of the Parties to the Montreal Protocol on Substances That Deplete the Ozone Layer. In carrying out the goals of the Montreal Protocol to phase out essential use exemptions of CFC MDI products, the Food and Drug Administration shall not prohibit the manufacture, sale, or distribution of any CFC MDI product on the basis that it is ''adulterated'' or ''misbranded.'' Any subsequent proposal shall be in the form of an advance notice of proposed rulemaking and shall be initiated only after extensive consultations with patients, physicians, other health

care providers, manufacturers of metered-dose inhalers, and other stakeholders.

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