105TH CONGRESS
2D SESSION

S. 2026

To require the Commissioner of Food and Drugs to conduct assessments and take other actions relating to the transition from use of chlorofluorocarbons in metered-dose inhalers, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 1, 1998

Mr. DEWINE (for himself and Mr. HUTCHINSON) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To require the Commissioner of Food and Drugs to conduct assessments and take other actions relating to the transition from use of chlorofluorocarbons in metered-dose inhalers, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Asthma Inhaler Protection Act''.

SEC. 2. ASSESSMENTS RELATED TO TRANSITION FROM USE OF CHLOROFLUOROCARBONS IN METERED-DOSE INHALERS.

(a) ASSESSMENTS.—Before beginning rulemaking to issue a regulation described in section 3(a), the Commissioner of Food and Drugs (referred to in this Act as the ''Commissioner'') shall conduct the following assessments concerning the transition from use of chlorofluorocarbons in metered-dose inhalers:

(1) An assessment of the health risks and benefits of the regulatory approach set forth in the advance notice of proposed rulemaking entitled ''Chlorofluorocarbon Propellants in Self-Pressurized Containers; Determinations That Uses Are No Longer Essential; Request for Comments'', published in the Federal Register on March 6, 1997, 62 Fed. Reg. 10242, and the health risks and benefits of alternative policies for facilitating the transition to non-chlorofluorocarbon treatments for asthma and other respiratory diseases.

(2) An assessment of the environmental risks and benefits of the regulatory approach set forth in the notice described in paragraph (1), and the environmental risks and benefits of alternative policies for facilitating the transition to non-

chlorofluorocarbon treatments for asthma and other respiratory diseases.

(3) An assessment of whether measures and recommendations adopted by the Tenth Meeting of the Parties to the Montreal Protocol on Substances That Deplete the Ozone Layer will, when implemented in the United States, facilitate the transition in the United States to non-chlorofluorocarbon treatments for asthma and other respiratory diseases by 2005 without increasing the health risks to patients of such diseases.

(b) BASIS FOR ASSESSMENTS.—

(1) HEALTH RISKS AND BENEFITS.—The Commissioner shall base the assessment described in subsection (a)(1) on factors including extensive consultations with patients, physicians, other health care providers, manufacturers of metered-dose inhalers, and other interested parties.

(2) ENVIRONMENTAL RISKS AND BENEFITS.—The Commissioner shall conduct the assessment described in subsection (a)(2) in a manner consistent with section 102(2) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)), and parts 10, 20, 25, 71 , 101, 170, 171, 312, 314, 511, 514, 570, 571, 601, 812, and 814 of title 21, Code of

Federal Regulations. In conducting such assessment, the Commissioner shall consult with the Administrator of the Environmental Protection Agency, the Administrator of the National Oceanic and Atmospheric Administration, and the Administrator of the National Aeronautics and Space Administration, as appropriate.

(c) REPORTS.—The Commissioner shall prepare and submit to Congress a report for each assessment and shall publish the reports in the Federal Register.

SEC. 3. RULEMAKING ON CHLOROFLUOROCARBONS IN METERED-DOSE INHALERS.

(a) REGULATION.—After completing the duties described in section 2, the Commissioner shall issue a regulation setting forth criteria for determining whether and in what cases particular chlorofluorocarbon metered-dose inhalers are necessary for purposes of eligibility for class I allowances under section 604(d) of the Clean Air Act (42 U.S.C. 7671c(d)) and, as a result, represent essential uses of class I substances under title VI of the Clean Air Act (42 U.S.C. 7671 et seq.).

(b) ALTERNATIVES.—The criteria described in section 3(a) shall ensure that a range of non-chlorofluorocarbon inhaler alternatives are available for each active moiety, to the extent consistent with title 35,

United States Code, and section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and that such alternatives are, for all populations of users, comparable to existing treatments (in existence on the date of issuance of the regulation) in terms of safety and effectiveness, use for therapeutic indications, dosage strength, delivery system, and sufficient availability to meet consumer needs.

(c) LIMITATIONS.—The criteria described in section 3(a) shall not utilize a therapeutic class approach. If a determination described in subsection (a) results in the withdrawal of a class I allowance for use of a chlorofluorocarbon in a type of inhaler, inhalers of the type involved that were introduced into interstate commerce prior to the date of the determination shall not be considered to be adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) solely on the basis of the withdrawal.

SEC. 4. APPROVALS OF NEW MEDICAL PRODUCTS CONTAINING CHLOROFLUOROCARBONS.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505A (21 U.S.C. 355a) the following:

"SEC. 505B. APPROVALS OF NEW DRUGS CONTAINING CHLOROFLUOROCARBONS.

''(a) PRELIMINARY ASSESSMENTS AND TERMINATIONS OF REVIEW.—Notwithstanding any other provision of this Act, with respect to any application submitted to the Secretary under subsection (b) or (j) of section 505 (21 U.S.C. 355) after December 31, 1998, for any drug containing chlorofluorocarbons, the Secretary shall conduct a preliminary assessment of such application to determine if the drug represents a significant therapeutic advance over products previously approved under this chapter. If the Secretary determines that the drug does not represent a significant therapeutic advance over such approved products, the Secretary shall terminate review of such application and not approve the application for the drug.

''(b) LIMITATIONS.—Subsection (a) shall not apply to a supplement to an application if the application was approved under subsection (c) or (j)(4) of section 505.

''(c) CONSTRUCTION.—Notwithstanding any other provision of this chapter, use of a drug containing chlorofluorocarbons in a chlorofluorocarbon metered-dose inhaler shall be subject to the regulation referred to in section 3(a) of the Asthma Inhaler Protection Act, regardless of whether an application or supplement for the drug

is approved under section 505 in accordance with this section.''.

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