

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Asthma Inhaler Pro-
5 tection Act”.

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

4 (a) ASSESSMENTS.—Before beginning rulemaking to
5 issue a regulation described in section 3(a), the Commis-
6 sioner of Food and Drugs (referred to in this Act as the
7 “Commissioner”) shall conduct the following assessments
8 concerning the transition from use of chlorofluorocarbons
9 in metered-dose inhalers:

10 (1) An assessment of the health risks and bene-
11 fits of the regulatory approach set forth in the ad-
12 vance notice of proposed rulemaking entitled
13 “Chlorofluorocarbon Propellants in Self-Pressurized
14 Containers; Determinations That Uses Are No
15 Longer Essential; Request for Comments”, pub-
16 lished in the Federal Register on March 6, 1997, 62
17 Fed. Reg. 10242, and the health risks and benefits
18 of alternative policies for facilitating the transition
19 to non-chlorofluorocarbon treatments for asthma
20 and other respiratory diseases.

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

1 chlorofluorocarbon treatments for asthma and other
2 respiratory diseases.

3 (3) An assessment of whether measures and
4 recommendations adopted by the Tenth Meeting of
5 the Parties to the Montreal Protocol on Substances
6 That Deplete the Ozone Layer will, when imple-
7 mented in the United States, facilitate the transition
8 in the United States to non-chlorofluorocarbon treat-
9 ments for asthma and other respiratory diseases by
10 2005 without increasing the health risks to patients
11 of such diseases.

12 (b) BASIS FOR ASSESSMENTS.—

13 (1) HEALTH RISKS AND BENEFITS.—The Com-
14 missioner shall base the assessment described in
15 subsection (a)(1) on factors including extensive con-
16 sultations with patients, physicians, other health
17 care providers, manufacturers of metered-dose inhal-
18 ers, and other interested parties.

19 (2) ENVIRONMENTAL RISKS AND BENEFITS.—
20 The Commissioner shall conduct the assessment de-
21 scribed in subsection (a)(2) in a manner consistent
22 with section 102(2) of the National Environmental
23 Policy Act of 1969 (42 U.S.C. 4332(2)), and parts
24 10, 20, 25, 71 , 101, 170, 171, 312, 314, 511, 514,
25 570, 571, 601, 812, and 814 of title 21, Code of

1 Federal Regulations. In conducting such assessment,
2 the Commissioner shall consult with the Adminis-
3 trator of the Environmental Protection Agency, the
4 Administrator of the National Oceanic and Atmos-
5 pheric Administration, and the Administrator of the
6 National Aeronautics and Space Administration, as
7 appropriate.

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

11 **SEC. 3. RULEMAKING ON CHLOROFLUOROCARBONS IN ME-**
12 **TERED-DOSE INHALERS.**

13 (a) REGULATION.—After completing the duties de-
14 scribed in section 2, the Commissioner shall issue a regula-
15 tion setting forth criteria for determining whether and in
16 what cases particular chlorofluorocarbon metered-dose in-
17 halers are necessary for purposes of eligibility for class
18 I allowances under section 604(d) of the Clean Air Act
19 (42 U.S.C. 7671c(d)) and, as a result, represent essential
20 uses of class I substances under title VI of the Clean Air
21 Act (42 U.S.C. 7671 et seq.).

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

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

8 (c) LIMITATIONS.—The criteria described in section
9 3(a) shall not utilize a therapeutic class approach. If a
10 determination described in subsection (a) results in the
11 withdrawal of a class I allowance for use of a
12 chlorofluorocarbon in a type of inhaler, inhalers of the
13 type involved that were introduced into interstate com-
14 merce prior to the date of the determination shall not be
15 considered to be adulterated or misbranded under the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321
17 et seq.) solely on the basis of the withdrawal.

18 **SEC. 4. APPROVALS OF NEW MEDICAL PRODUCTS CON-**
19 **TAINING CHLOROFLUOROCARBONS.**

20 Chapter V of the Federal Food, Drug, and Cosmetic
21 Act is amended by inserting after section 505A (21 U.S.C.
22 355a) the following:

1 **“SEC. 505B. APPROVALS OF NEW DRUGS CONTAINING**
2 **CHLOROFLUOROCARBONS.**

3 “(a) PRELIMINARY ASSESSMENTS AND TERMI-
4 NATIONS OF REVIEW.—Notwithstanding any other provi-
5 sion of this Act, with respect to any application submitted
6 to the Secretary under subsection (b) or (j) of section 505
7 (21 U.S.C. 355) after December 31, 1998, for any drug
8 containing chlorofluorocarbons, the Secretary shall con-
9 duct a preliminary assessment of such application to de-
10 termine if the drug represents a significant therapeutic ad-
11 vance over products previously approved under this chap-
12 ter. If the Secretary determines that the drug does not
13 represent a significant therapeutic advance over such ap-
14 proved products, the Secretary shall terminate review of
15 such application and not approve the application for the
16 drug.

17 “(b) LIMITATIONS.—Subsection (a) shall not apply to
18 a supplement to an application if the application was ap-
19 proved under subsection (c) or (j)(4) of section 505.

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

1 is approved under section 505 in accordance with this sec-
2 tion.”.

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