

[DISCUSSION DRAFT]

112TH CONGRESS  
2D SESSION

**H. R.** \_\_\_\_\_

To direct the Administrator of the Environmental Protection Agency to allow for the distribution, sale, and consumption in the United States of remaining inventories of over-the-counter CFC epinephrine inhalers.

---

IN THE HOUSE OF REPRESENTATIVES

M. \_\_\_\_\_ introduced the following bill; which was referred to the Committee on \_\_\_\_\_

---

**A BILL**

To direct the Administrator of the Environmental Protection Agency to allow for the distribution, sale, and consumption in the United States of remaining inventories of over-the-counter CFC epinephrine inhalers.

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 Inhalers Relief  
5 Act of 2012”.

1 **SEC. 2. DISTRIBUTION, SALE, AND CONSUMPTION OF RE-**  
2 **MAINING INVENTORIES OF OVER-THE-**  
3 **COUNTER CFC EPINEPHRINE INHALERS.**

4 (a) IN GENERAL.—The Administrator of the Envi-  
5 ronmental Protection Agency—

6 (1) shall allow for the distribution, sale, and  
7 consumption in the United States of remaining in-  
8 ventories of CFC epinephrine inhalers manufactured  
9 pursuant to the exception for medical devices under  
10 section 604(d)(2) of the Clean Air Act (42 U.S.C.  
11 7671e(d)(2));

12 (2) shall not take any enforcement action or  
13 otherwise seek to restrict the distribution, sale, or  
14 consumption of such inhalers on the basis of any  
15 Federal law implementing the Montreal Protocol;  
16 and

17 (3) shall, in response to any request of any dis-  
18 tributor or seller of such inhalers, including any  
19 such request pending on the date of the enactment  
20 of this Act, issue a No Action Assurance Letter to  
21 the requesting party stating that the Environmental  
22 Protection Agency will not initiate an enforcement  
23 action relating to the distribution or sale of any such  
24 inhaler occurring prior to August 1, 2013.

25 (b) RULE OF CONSTRUCTION.—Nothing in this Act  
26 shall be construed to limit or otherwise affect the authority

1 of the Food and Drug Administration under the Federal  
2 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)  
3 to ensure the safety and effectiveness of CFC epinephrine  
4 inhalers to be distributed, sold, or consumed pursuant to  
5 this Act.

6 (c) DEFINITIONS.—In this Act:

7 (1) The term “CFC epinephrine inhaler” means  
8 any epinephrine inhaler containing  
9 chlorofluorocarbons that was manufactured and clas-  
10 sified as over-the-counter before January 1, 2012.

11 (2) The phrase “Federal law implementing the  
12 Montreal Protocol”—

13 (A) means any provision of title VI of the  
14 Clean Air Act (42 U.S.C. 7671 et seq.) or other  
15 Federal law implementing the Montreal Pro-  
16 tocol; and

17 (B) includes the final rule published by the  
18 Food and Drug Administration entitled “Use of  
19 Ozone-Depleting Substances; Removal of Essen-  
20 tial-Use Designation (Epinephrine)” published  
21 in the Federal Register at 73 Federal Register  
22 69532 (November 19, 2008).

23 (3) The term “Montreal Protocol” has the  
24 meaning given such term in section 601 of the Clean  
25 Air Act (42 U.S.C. 7671).

1           (4) The term “over-the-counter” means not  
2           subject to section 503(b)(1) of the Federal Food,  
3           Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)) or  
4           otherwise required pursuant to Federal law to be  
5           dispensed only upon issuance of a prescription.

6           (d) SUNSET.—This section ceases to be effective Au-  
7           gust 1, 2013.