

## Union Calendar No. 485

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 6190

[Report No. 112-673]

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

JULY 25, 2012

Mr. BURGESS (for himself, Mr. ROSS of Arkansas, Mr. BARTON of Texas, Mr. PITTS, Mr. CARTER, and Mr. MATHESON) introduced the following bill; which was referred to the Committee on Energy and Commerce

SEPTEMBER 14, 2012

Committed to the Committee of the Whole House on the State of the Union  
and ordered to be printed

# **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”.

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

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

11           (1) shall allow for the distribution, sale, and  
12 consumption in the United States of remaining in-  
13 ventories of CFC epinephrine inhalers manufactured  
14 pursuant to the exception for medical devices under  
15 section 604(d)(2) of the Clean Air Act (42 U.S.C.  
16 7671c(d)(2));

17           (2) shall not take any enforcement action or  
18 otherwise seek to restrict the distribution, sale, or  
19 consumption of such inhalers on the basis of any  
20 Federal law implementing the Montreal Protocol;  
21 and

22           (3) shall, in response to any request of any dis-  
23 tributor or seller of such inhalers, including any  
24 such request pending on the date of the enactment  
25 of this Act, issue a No Action Assurance Letter to

1 the requesting party stating that the Environmental  
2 Protection Agency will not initiate an enforcement  
3 action relating to the distribution or sale of any such  
4 inhaler occurring prior to August 1, 2013.

5 (b) RULE OF CONSTRUCTION.—Nothing in this Act  
6 shall be construed to limit or otherwise affect the authority  
7 of the Food and Drug Administration under the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)  
9 to ensure the safety and effectiveness of CFC epinephrine  
10 inhalers to be distributed, sold, or consumed pursuant to  
11 this Act.

12 (c) DEFINITIONS.—In this Act:

13 (1) The term “CFC epinephrine inhaler” means  
14 any epinephrine inhaler containing chlorofluorocar-  
15 bons that was manufactured and classified as over-  
16 the-counter before January 1, 2012.

17 (2) The phrase “Federal law implementing the  
18 Montreal Protocol”—

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

23 (B) includes the final rule published by the  
24 Food and Drug Administration entitled “Use of  
25 Ozone-Depleting Substances; Removal of Essen-

1            tial-Use Designation (Epinephrine)” published  
2            in the Federal Register at 73 Federal Register  
3            69532 (November 19, 2008).

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

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

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

Union Calendar No. 485

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**H. R. 6190**

[Report No. 112-673]

---

---

## **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.

---

---

SEPTEMBER 14, 2012

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed