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Union Calendar No. 485

112TH CONGRESS
2D 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.

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 Inhalers Relief Act of 2012''.

SEC. 2. DISTRIBUTION, SALE, AND CONSUMPTION OF REMAINING INVENTORIES OF OVER-THE-COUNTER CFC EPINEPHRINE INHALERS.

(a) IN GENERAL.—The Administrator of the Environmental Protection Agency—

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

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

(3) shall, in response to any request of any distributor or seller of such inhalers, including any such request pending on the date of the enactment of this Act, issue a No Action Assurance Letter to

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

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

(c) DEFINITIONS.—In this Act:

(1) The term ''CFC epinephrine inhaler'' means any epinephrine inhaler containing chlorofluorocarbons that was manufactured and classified as over-the-counter before January 1, 2012.

(2) The phrase ''Federal law implementing the Montreal Protocol''—

(A) means any provision of title VI of the Clean Air Act (42 U.S.C. 7671 et seq.) or other Federal law implementing the Montreal Protocol; and

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

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

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

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

(d) SUNSET.—This section ceases to be effective August 1, 2013.

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