DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 16 2011

Read 5/16/2011

J. Martin Carroll
President & CEO
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
Ridgefield, CT 06877

Re: Docket No. FDA-2006-P-0204

Dear Mr. Carroll:

This letter responds to your citizen petition (petition) received on October 23, 2006.[1] You request that the Food and Drug Administration (FDA) refrain temporarily from taking action to remove chlorofluorocarbon (CFC) propelled metered-dose inhalers containing albuterol and ipratropium bromide in combination (marketed as COMBIVENT) from the list of essential uses of ozone-depleting substances (ODSs). Specifically, you state that removal of the essential-use status of COMBIVENT before a CFC-free version is available will create a gap in the product's availability and thereby impose unnecessary disruption for patients. For the reasons stated below, your petition is denied because your request is moot.

On June 11, 2007, FDA published a proposed rule in the *Federal Register* (72 FR 32030) (proposed rule) proposing to remove the essential-use designation for oral pressurized metered-dose inhalers containing albuterol and ipratropium in combination, among other products. After considering information received at an August 2, 2007, public meeting and written comments submitted in response to the proposed rule, FDA issued a final rule entitled "Use of Ozone-Depleting Substances; Removal of Essential-Use Designation (Flunisolide, etc.)" (75 FR 19213) (final rule) in the *Federal Register* on April 14, 2010. In the final rule, FDA concluded that products containing albuterol and ipratropium bromide in combination no longer meet the criteria to be essential uses of ODSs, and they must be removed from the market by December 31, 2013.

Your petition is moot because FDA has already taken action to remove metered-dose inhalers containing albuterol and ipratropium bromide in combination from the list of essential uses of ODSs in 21 CFR § 2.125. As discussed in the final rule, FDA has

[1] This citizen petition was originally assigned docket number 2006P-0428/CP1. The number was changed to FDA-2006-P-0204 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

FDA-2006-P-0204

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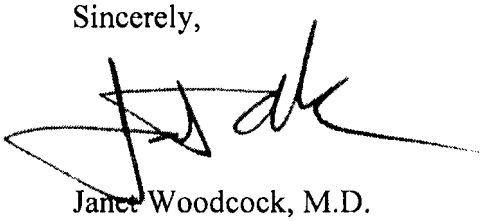
concluded that there are no substantial technical barriers to formulating albuterol and ipratropium in combination as products that do not release ODSs. The effective date for the removal of the essential-use designation for albuterol and ipratropium bromide in combination provides ample time to disseminate information about the transition to patients, and for patients and healthcare providers to evaluate their options and transition to appropriate therapeutic alternatives. This effective date also gives sufficient time for the development and approval of a non-CFC formulation of a combination product containing albuterol and ipratropium. For these reasons, we consider the relief requested in your petition to be moot, and your petition is denied.

Sincerely,



Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research