

**FINDING OF NO SIGNIFICANT IMPACT**

**and**

**ENVIRONMENTAL ASSESSMENT**

**for**

**Removing the Essential-Use Designation under  
21 CFR 2.125 for the Following Human Drug Products**

**Oral Pressurized Metered-Dose Inhalation Products  
Containing:**

- Flunisolide
- Triamcinolone
- Metaproterenol
  - Pirbuterol
- Albuterol and Ipratropium in Combination
  - Cromolyn
- Nedocromil Bromide

**CENTER FOR DRUG EVALUATION AND RESEARCH  
FOOD AND DRUG ADMINISTRATION**

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The National Environmental Policy Act of 1969 (NEPA) requires all Federal agencies to assess the environmental impact of their actions. Under the Clean Air Act (CAA), the Food and Drug Administration (FDA) in consultation with the Environmental Protection Agency (EPA) is required to determine whether an FDA-regulated product that contains an ozone-depleting substance (ODS), such as chlorofluorocarbons (CFCs), is essential. The regulations at 21 CFR 2.125, *Use of ozone-depleting substances in foods, drugs, devices, or cosmetics*, provide standards that FDA uses to determine which FDA regulated products that contain an ODS are essential under the CAA. This Environmental Assessment (EA) constitutes the agency's environmental review for removing the essential-use designations under 21 CFR 2.125(g)(1) for certain drug products.

FDA is amending its regulation (21 CFR 2.125) on the use of ozone-depleting substances in pressurized containers to remove essential-use designations for oral pressurized metered-dose inhalers (MDIs) containing flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil bromide.

The essential-use designations for these products are being removed because we have tentatively concluded that oral pressurized MDIs containing flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil are no longer an essential use of ODSs. Once the essential-use designations are removed, flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil bromide MDIs containing ODSs cannot be marketed, and any adverse environmental effects from the ODSs will be eliminated. Therapeutic alternatives that do not use an ODS are currently marketed and appear to provide all of the important public health benefits of the listed drugs.

The Center for Drug Evaluation and Research has carefully considered the potential environmental impact of removing the essential-use designations for the identified products and has concluded that this action will not have, individually or cumulatively, a significant effect on the quality of the human environment and therefore an environmental impact statement is not required.

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6/01/07 *R.A. Bloom*  
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Attachment: Environmental Assessment