

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 Epinephrine**

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

2007N-0262

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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 an essential product. 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 designation 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 designation for oral pressurized metered-dose inhalers (MDIs) containing epinephrine.

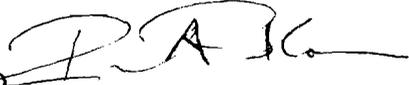
The essential-use designation for these products is being removed because we have tentatively concluded that oral pressurized MDIs containing epinephrine are no longer an essential use of ODSs. Once the essential-use designation is removed, epinephrine MDIs containing an ODS cannot be marketed, and any adverse environmental effects from the ODS used in these products will be eliminated.

The Center for Drug Evaluation and Research has carefully considered the potential environmental impact of removing the essential-use designation 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.

7-31-07

DATE

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Attachment: Environmental Assessment