ENVIRONMENTAL ASSESSMENT

1. Date

May 31, 2007

2. Agency Preparing the Environmental Assessment (EA)

Center for Drug Evaluation and Research
Food and Drug Administration

3. Address

5600 Fishers Lane
Rockville, MD 20857

4. Description of the Proposed Action

The Food and Drug Administration (FDA) is amending its regulation on the use of ozone-depleting substances (21 CFR 2.125) to remove the essential-use designations for certain human drug products.

This EA evaluates the potential environmental impacts of removing the essential-use designations for the human drug products identified in section 5, below.

5. Identification of Substances that are the Subject of the Proposed Action

Essential-use designations will be removed for oral pressurized metered-dose inhalers (MDIs) containing flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil bromide.

6. Environmental Issues

A. Background

In 1978, FDA finalized a programmatic environmental impact statement (EIS) regarding the use of chlorofluorocarbons (CFCs) in products subject to regulation by the agency under the Federal Food, Drug, and Cosmetic Act. This EIS was used as the basis for prohibiting use of CFCs as propellants in self-pressurized containers if the use of the CFC was not deemed to be essential. As stated in the EIS:

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> The Commissioner of Food and Drugs has concluded that the continued use of chlorofluorocarbons propellants in self-pressurized containers in products subject to the Federal Food, Drug, and Cosmetic Act (FFD&C) poses an unreasonable risk of long-term biological and climatic impacts.
>
> Accordingly, the Food and Drug Administration is finalizing a prohibition of the nonessential use of chlorofluorocarbons as propellants in self-pressurized (aerosolized) containers in products subject to the FFD&C Act. The products to which the regulation applies are human food, food additives, human drugs (including biological products), animal food, animal drugs, cosmetics, and medical devices. (p. iii).

Subsequent to this action, Congress enacted the Clean Air Act (CAA), designed in part to phase out the use of ozone-depleting substances in the United States. Under the CAA, 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),[1] such as CFC, is essential.

The regulations at 21 CFR 2.125, *Use of ozone-depleting substances in foods, drugs, devices, or cosmetics*, provides standards that FDA uses to determine which FDA regulated products that contain an ODS are essential under the CAA. This EA constitutes the agency's environmental review for removal of essential-use designations for identified products under 21 CFR 2.125(g)(1).

B. Environmental Effects of Removing Essential-Use Designation

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 bromide 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. It is estimated that the emissions of CFCs will be reduced by between 310 and 365 tonnes (see Proposed Rule). 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.

[1] Any class I substance as defined in 40 CFR part 82, appendix A to subpart A, or class II substance as defined in 40 CFR part 82, appendix B to subpart A.

C. Summary

FDA's removal of essential-use designations for the identified products is not expected to have the potential for adverse environmental effects and thus no significant adverse environmental impact.

7. Mitigation Measures

No potential adverse environmental effects have been identified as a consequence of removing the essential-use designations for the specified products and, therefore, no mitigation measures are required.

8. Alternatives to the Proposed Action

No potential adverse environmental effects have been identified; therefore, no alternatives to the proposed action have been identified.

9. List of Preparers

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10. References

Final Environmental Impact Statement; Fluorocarbons: Environmental and Health Implications (Docket # 96N-0057)

21 CFR 2.125: *Use of ozone-depleting substances in foods, drugs, devices, or cosmetics.*

11. Appendices

None