DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 28 2003

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Fran Du Melle
Executive Vice President
American Lung Association
1150 18th Street, NW Suite, 900
Washington, DC 20036

Re: Docket No. 03P-0029

Dear Ms. Du Melle:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted on January 29, 2003, on behalf of the U.S. Stakeholders Group on MDI Transition. Your petition requests that the Agency initiate rulemaking to amend 21 C.F.R. 2.125(e)(2) by removing drug products containing the active moiety albuterol from the list of drug products in which use of an ozone depleting substance is essential.

FDA has been unable to reach a decision on your petition because it raises significant and complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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