

To DMS...

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. 2003P-0029]

RIN 0910-AF18

REFERENCES
1-15
for

Max!
Diary
Sullivan

Use of Ozone-Depleting Substances; Removal of Essential-Use Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulation on the use of ozone-depleting substances (ODSs) in self-pressurized containers to remove the essential-use designations for albuterol used in oral pressurized metered-dose inhalers (MDIs). Under the Clean Air Act, FDA, in consultation with the Environmental Protection Agency (EPA), is required to determine whether an FDA-regulated product that releases an ODS is an essential use of the ODS. Two albuterol MDIs that do not use an ODS are currently marketed. FDA has tentatively determined that the two non-ODS MDIs will be satisfactory alternatives to albuterol MDIs containing ODSs and are proposing to remove the essential-use designation for albuterol MDIs. If the essential-use designation is removed, albuterol MDIs containing an ODS could not be marketed after a suitable transition period.

DATES: Submit written or electronic comments by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: You may submit comments, identified by [Docket No. 2003P-0029], by any of the following methods:

CD 03154

BKG 1