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APPLICATION NUMBER: 20-746

ENVIRONMENTAL ASSESSMENT AND/OR FONSI

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ENVIRONMENTAL ASSESSMENT REPORT

1. Date: September 30, 1997
- 2) Name of Applicant: Astra USA, Inc.
3. Address: Astra USA, Inc.
Otis Street
Westborough, MA 01581

4. Description of the Proposed Action:

Astra USA, Inc. has filed a New Drug Application pursuant to Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act requesting approval of Rhinocort® Aqua Nasal Spray, 32µg/dose and 64µg/dose, packaged in a pump spray glass bottle. Rhinocort® Aqua is intended for use for the management of symptoms for seasonal and perennial allergic rhinitis.

5. Request for Categorical Exclusion:

The applicant requests a categorical exclusion pursuant to 21 CFR 25.31(b) for the action described above.

6. Certification:

The applicant certifies that the action described above increases the use of the active moiety (budesonide), but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion.

/S/

9/30/97
Date

Daniel M. Duffy, Jr.
Plant Engineer, Operations
Astra USA, Inc.

APPEARS THIS WAY
ON ORIGINAL