

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 20-989

ENVIRONMENTAL ASSESSMENT AND/OR FONSI

SnowBrand Pharmaceuticals, Inc.
Cevimeline Hydrochloride

NEW DRUG APPLICATION
4. CHEMISTRY AND MANUFACTURING

4.7. Environmental Assessment

4.7.1. Claim for Categorical Exclusion

The requested action, approval of NDA 20-989, qualifies for a categorical exclusion for the requirement to prepare an environmental assessment under 21 CFR 25.31(b). To the applicant's knowledge, no extraordinary circumstances exist that would warrant the preparation of an environmental assessment.

Based on 5th year marketing estimates, the estimate of the active moiety cevimeline hydrochloride expected to enter the aquatic environment of the United States is below 1 part per billion.

APPEARS THIS WAY
ON ORIGINAL