

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-077

ENVIRONMENTAL ASSESSMENT and/or FONSI

ENVIRONMENTAL ASSESSMENT

**Statement Of Categorical Exclusion
For
Salmeterol/Fluticasone Propionate Diskus**

DATE: March 30, 1999

APPLICANT: Glaxo Wellcome Inc.

ADDRESS: Five Moore Drive
Research Triangle Park, NC 27709

STATEMENT: The proposed action is subject to the categorical exclusion listed in 21 CFR Part 25.31(b). Glaxo Wellcome has reviewed market forecasts, indications and dosage information and estimates that this action will not cause the concentration of the drug substance active moiety to be one part per billion (1 ppb) or greater at the point of entry into the aquatic environment. Glaxo Wellcome does not have knowledge of any extraordinary circumstances that might cause this action to have a significant affect on the quality of the human environment.

**APPEARS THIS WAY
ON ORIGINAL**