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.