

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205434Orig1s000

ENVIRONMENTAL ASSESSMENT

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Statement of Categorical Exclusion
For
Fluticasone Propionate Aqueous Nasal Spray
Fluticasone propionate

DATE: July 16, 2013

APPLICANT: GlaxoSmithKline Consumer Healthcare

ADDRESS: 1500 Littleton Road
Parsippany, NJ 07054

STATEMENT: The proposed action is subject to the categorical exclusion listed in 21 CFR Part 25.31(b). GlaxoSmithKline 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. GlaxoSmithKline 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.