

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**22-051**

**ENVIRONMENTAL ASSESSMENT**

**CONFIDENTIAL**

m1.12.14 Environmental Analysis

**ENVIRONMENTAL ASSESSMENT**

**Statement of Categorical Exclusion**

**For**

**Fluticasone Furoate Nasal Spray**

**DATE:** June 23<sup>rd</sup>, 2006

**APPLICANT:** GlaxoSmithKline

**ADDRESS:** One Franklin Plaza  
P.O. Box 7929  
Philadelphia, PA 19101

**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.

**APPEARS THIS WAY  
ON ORIGINAL**