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APPLICATION NUMBER:

205625Orig1s000

ENVIRONMENTAL ASSESSMENT

GlaxoSmithKline submitted a claim of categorical exclusion from the requirement to prepare an environmental assessment (EA) for Fluticasone Furoate Inhalation Powder. Fluticasone Furoate is an inhaled corticosteroid (ICS) with anti inflammatory activity indicated for maintenance treatment of asthma as prophylactic .

I have reviewed the claim and determined that the application qualifies for a categorical exclusion under 21 CFR 25.31 (b). No extraordinary circumstances are indicated. No further action is required.

Raanan A. Bloom, Ph.D.

OPS/ONDQA/EA Staff

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/s/

RAANAN A BLOOM
07/30/2014