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APPLICATION NUMBER:

NDA 21-254

SUMMARY REVIEW

DIVISION DIRECTOR'S MEMORANDUM

Date: June 8, 2006

To: NDA 21-254

From: Badrul A. Chowdhury, MD, PhD
Director, Division of Pulmonary and Allergy Drug products, HFD-570

Product: Advair HFA 45/21 (fluticasone propionate 45 mcg and salmeterol 21 mcg) Inhalation Aerosol, Advair HFA 115/21 (fluticasone propionate 115 mcg and salmeterol 21 mcg) Inhalation Aerosol, and Advair HFA 230/21 (fluticasone propionate 45 mcg and salmeterol 21 mcg) Inhalation Aerosol

Applicant: GlaxoSmithKline

The NDA for Advair HFA Inhalation Aerosol originally submitted by GlaxoSmithKline (GSK) on December 20, 2000, received an approvable action on October 19, 2001, primarily due to CMC issues. In this resubmission dated December 7, 2005, all major CMC issues that precluded approval have been resolved. There are some minor CMC issues that GSK has committed to address post-approval. Some of these include continued effort to examine the _____ and minimize it as much as possible, _____, and evaluate Parametric Tolerance Interval Test approach for dose content uniformity once an adequate database is available. The CMC team is recommending an approval action pending an acceptable EES status from the Office of Compliance and I concur with that recommendation. The Office of Compliance, on June 2, 2006, has issued an acceptable status for all sites listed in the NDA.

During this review cycle various disciplines of this Division, DMETS and DSRCS of the Office of Surveillance and Epidemiology, and DDMAC reviewed the product label. Some changes to label were done to better reflect the data and better communicate the finding to health care providers. GSK and the Division have agreed upon a final labeling text, and carton and closure labeling text and the presentations. It should be noted that GSK developed Advair Inhalation Aerosol as a stand alone product and not as a switch product linking to Advair Diskus. Therefore, the label of this product is unique and primarily relies on clinical studies conducted specifically with Advair HFA Inhalation Aerosol.

There are no other outstanding issues with any disciplines. The action on this application will be APPROVAL.

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/s/

Badrul Chowdhury
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MEDICAL OFFICER