CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-077/S050

Trade Name: Advair Diskus®

Generic Name: fluticasone propionate; salmeterol xinafoate

Sponsor: GlaxoSmithKline

Approval Date: 6/19/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-077/S050

CONTENTS

Reviews / Information Included in this NDA Review.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-077/S050

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20121/S-041, 20833/S-027, 21077/S-050, 21254/S-020, and 21433/S-021

APPROVAL LETTER

Glaxo Group Limited d/b/a GlaxoSmithKline
Attention: Purnima Narang
Assistant Director, CMC Regulatory Affairs
Five Moore Drive, PO Box 13398
Research Triangle Park, NC 27709

Dear Ms. Narang:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received December 19, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following.

NDA#	Supplement#	Product Description
20121	S-041	Flonase® (fluticasone propionate) Nasal Spray
20833	S-027	Flovent® Diskus (fluticasone propionate) Inhalation Powder
21077	S-050	Advair® Diskus (fluticasone propionate/salmeterol) Inhalation Powder
21254	S-020	Advair® HFA (fluticasone propionate/salmeterol) Inhalation Aerosol
21433	S-021	Flovent® HFA (fluticasone propionate) Inhalation Aerosol

These "Changes Being Effected in 30 days" supplemental applications propose the following changes.

1. Addition of the GSK. (b) (4)
2. Use of a (b) (4)
3. Revised (b) (4) Specifically the changes are:
   a. Addition o (b) (4)

b. In comparison to the (b) (4) (b) (4)

4. Modification of the (b) (4)

We have completed our review of these supplemental new drug applications. These supplements are approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Youbang Liu, Regulatory Project Manager, at (301) 796-1926.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Acting Branch Chief, Branch IX
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

RAMESH RAGHAVACHARI
06/19/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-077/S050

CHEMISTRY REVIEW(S)

NDA 20-121, S-041
NDA 20-833, S-027
NDA 21-077, S-050
NDA 21-254, S-020
NDA 21-433, S-021

DIVISION OF NEW DRUG QUALITY ASSESSMENT III
POST-MARKETING, BRANCH IX
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-121 **DATE REVIEWED:** 6/18/2013
NDA #: 20-833
NDA #: 21-077
NDA #: 21-254
NDA #: 21-433

OND: DPARP

REVIEW #: 1 **REVIEWER:** Donald N. Klein, Ph.D.

SUBMISSION TYPE	CDER DATE
CBE-30	12/19/2012

NAME & ADDRESS OF APPLICANT:

Glaxo Group Limited d/b/a GlaxoSmithKline
Glaxo Wellcome House
Berkeley Avenue
Greenford, Middlesex
UB6 0NN England

U.S. Agent:
Purnima Narang
Assistant Director, CMC Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

DRUG PRODUCT NAME:

N20-121:

Proprietary: Flonase®
Established (1985): Fluticasone Propionate, USP

N20-833:

Proprietary: Flovent Diskus®
Established (1985): Fluticasone Propionate, USP

N21-077:

Proprietary: Advair Diskus®
Established (1985): Fluticasone Propionate, USP
Established (1985): Salmeterol

N21-254:

Proprietary: Advair™ HFA
Established (1985): Fluticasone Propionate, USP
Established (1985): Salmeterol

N21-433:

Proprietary: Flovent® HFA
Established (1985): Fluticasone Propionate, USP

PHARMACOL. CATEGORY/INDICATION:

N20-121: Prophylaxis and treatment of seasonal and perennial rhinitis

N20-833: Maintenance treatment of asthma as prophylactic therapy

N21-077: Maintenance treatment of asthma in patients 12 years of age and older

N21-254: Maintenance treatment of asthma in patients 12 years of age and older

N21-433: Maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older

DOSAGE FORM:
N20-121: Nasal spray

N20-833: Inhaler

N21-077: Inhaler

N21-254: Inhalation aerosol

N21-433: Inhalation aerosol

STRENGTHS:
N20-121: 50 mcg

N20-833: 50 mcg, 100 mcg, and 250 mcg

N21-077: 100 mcg/50 mcg; 250 mcg/50 mcg; and 500 mcg/50 mcg

N21-254: 45 mcg/21 mcg; 115 mcg/21 mcg; and 230 mcg/21 mcg

N21-433: 44 mcg, 110 mcg and 220 mcg

ROUTE OF ADMINISTRATION:
N20-121: Intranasal

N20-833: Oral inhalation

N21-077: Oral inhalation

N21-254: Oral inhalation

N21-433: Oral inhalation

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SUPPLEMENT PROVIDES FOR:

1. Addition of the GSK, [redacted]
2. Use of a [redacted]
3. Revised [redacted] Specifically the changes are:
   a. Addition of [redacted]
   b. In comparison to the [redacted]
4. In comparison to [redacted]

CONCLUSION: Recommend Approval.

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/s/

DONALD N KLEIN
06/18/2013
Revised as discussed; Recommend Approval; 5 Grouped CBE-30s DUE 6/19/2013

RAMESH RAGHAVACHARI
06/18/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-077/S050

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20121/S-041, 20833/S-027, 21077/S-050, 21254/S-020, and 21433/S-021

CBE-30 SUPPLEMENT

Glaxo Group Limited d/b/a GlaxoSmithKline
Attention: Purnima Narang
Assistant Director, CMC Regulatory Affairs
Five Moore Drive, PO Box 13398
Research Triangle Park, NC 27709

Dear Ms. Narang:

We have received your Supplemental New Drug Applications (sNDA) submitted and received December 19, 2012 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

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These “Changes Being Effected in 30 days” supplemental applications propose the following changes.

Unless we notify you within 60 days of the receipt date that the applications are not sufficiently complete to permit a substantive review, we will file the applications on February 17, 2013 in accordance with 21 CFR 314.101(a). If the applications are filed, the user fee goal date will be June 19, 2013.

Please cite the application numbers listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Pulmonary, Allergy, and Rheumatology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have questions, call me at (301) 796-1926.

Sincerely,

{See appended electronic signature page}

Youbang Liu
Regulatory Project Manager
Division III of New Drug Quality Assessment
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

YOUBANG LIU
01/17/2013