APPLICATION NUMBER:
21-077/S050

Trade Name: Advair Diskus®

Generic Name: fluticasone propionate; salmeterol xinafoate

Sponsor: GlaxoSmithKline

Approval Date: 6/19/2013
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<th>Reviews / Information Included in this NDA Review.</th>
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
21-077/S050

APPROVAL LETTER
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.

<table>
<thead>
<tr>
<th>NDA#</th>
<th>Supplement#</th>
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<tbody>
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<td>20121</td>
<td>S-041</td>
<td>Flonase® (fluticasone propionate) Nasal Spray</td>
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<td>Advair® HFA (fluticasone propionate/salmeterol) Inhalation Aerosol</td>
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</table>

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

1. Addition of the GSK.
2. Use of a
3. Revised
   a. Addition

Specifically the changes are:

Reference ID: 3327710
b. In comparison to the

4. Modification of the

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
CHEMISTRY REVIEW(S)
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

1 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page
SUPPLEMENT PROVIDES FOR:

1. Addition of the GSK,

2. Use of a

3. Revised

   Specifically the changes are:
   a. Addition of
   b. In comparison to the

4. In comparison to

CONCLUSION: Recommend Approval.

18 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page
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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
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
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

YOUBANG LIU
01/17/2013