



NDA 21-912/S-016

**SUPPLEMENT APPROVAL**

Sunovion Pharmaceutical Inc.  
Attention: John Salveta  
Director, CMC Regulatory Affairs  
84 Waterford Drive  
Marlborough, MA 01752-7010

Dear Mr. Salveta:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 4, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Brovana® (arformoterol tartrate) Inhalation Solution.

We acknowledge receipt of your amendment dated August 25, 2011.

This “Changes Being Effected in 30 days” supplemental new drug application proposes the following change(s):

- 1) Reducing the size, and revising the layout of the 4-vial pouches for Trade and Sample drug products
- 2) Reducing the size, and revising the text layout of the 4-vial secondary packaging cartons for Trade and Sample drug products
- 3) Revising the design of the 4-vial secondary packaging carton for Trade drug product.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

Submit final printed carton and container labels that are identical to the enclosed immediate container labels submitted on March 4, 2011, except with the revisions listed below.

- For Carton labeling (60 count):  
Revise and increase the font of the Medication Guide statement to be at least that of the “Potency expressed” statement on the principal display panel.

We remind you of your agreement dated August 25, 2011 to make the revision described above in your next printing and submit them in the next annual report.

We also remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Swati Patwardhan, Regulatory Project Manager, at (301) 796-4085.

Sincerely,

*{See appended electronic signature page}*

Eric Duffy, Ph.D.  
Division Director  
Division of New Drug Quality Assessment III  
Office of New Drug Quality Assessment  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Carton and Container Labeling

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/s/  
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ERIC P DUFFY  
09/02/2011