U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

Statistical Review and Evaluation

CLINICAL STUDIES

NDA/Serial Number:	21-254/S0009
Drug Name:	Advair® HFA (fluticasone propionate/salmeterol) Inaltion Aerosol 45mcg/21mcg, 115mcg/21mcg, 230mcg/21mcg
Indication(s):	(b) (4) treatment of asthma in Patients aged 12 years and older
Applicant:	GSK
Date(s):	Received 7/9/10
Review Priority:	S
Biometrics Division:	Division of Biometrics II/Office of Biostatistics
Statistical reviewer:	Feng Zhou, M.S.
Concurring reviewers:	Joan Buenconsejo, Ph.D.
Medical Division:	Division of Pulmonary, Allergy, and Rheumatology Products
Clinical Team:	Han Sarro, Xuemeng, M.D. (Medical Reviewer) Durmowicz, Anthony, M.D. (Medical Team Leader) Chowdhury, Badrul A, M.D., Ph.D. (Medical Division Director)
Project Manager:	Hill, Carol

Keywords: Labeling

Advair® HFA (fluticasone propionate/salmeterol) Inhalation Aerosol was approved in US (NDA 21-254) on June 8, 2006. As per FDA Guidance to Industry: Providing Regulatory Submissions in Electronic Format Content of Labeling in accordance with 21 CFR 314.70(b) and the January 24, 2006 Final Rule on Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products (21 CFR 201.57), the sponsor, GSK, submitted revised labeling for Advair® HFA in PLR format on June 25, 2009. GSK submitted a labeling amendment on July 9, 2010 that incorporates changes approved by FDA on June 25, 2010 (NDA 21-254-S013) regarding LABA safety issues. On January 31, 2011, GSK submitted an amendment to provide updated draft labeling that incorporates changes approved by FDA on January 4, 2011.

Upon reviewing the clinical studies section of the label, nothing appears to have changed. Thus, I have no statistical comments.

-EOF-

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

FENG ZHOU
02/08/2011

JOAN K BUENCONSEJO
02/08/2011
I concur with Feng Zhou's review.