Statistical Review and Evaluation

CLINICAL STUDIES

NDA/Serial Number: 21-254/S0009
Drug Name: Advair® HFA (fluticasone propionate/salmeterol) Inhalar Aerosol 45mcg/21mcg, 115mcg/21mcg, 230mcg/21mcg
Indication(s): 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
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Keywords: Labeling

Reference ID: 2902540
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.
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/s/

FENG ZHOU
02/08/2011

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