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

sNDA/Serial Number:	sNDA20-762/ (b) (4)
Drug Name:	Nasonex (mometasone furoate) Nasal Spray 50mcg
Indication(s):	(b) (4) supplement for treatment of pediatric nasal polyps pediatric patients 6 – 17 years of age
Applicant:	Schering-Plough
Date(s):	Received 03/19/10; User Fee 01/19/11
Review Priority:	10-months
Biometrics Division:	Division of Biometrics II/Office of Biostatistics
Statistical Team:	Zhou, Feng, M.S. (Statistical Reviewer) Joan Buenconsejo, Ph.D. (Acting Statistical Team Leader) Permutt, Thomas J, Ph.D. (Division Director of Biometrics II)
Medical Division:	Division of Pulmonary, Allergy, and Rheumatology Products
Clinical Team:	Porter, Brian, M.D. (Medical Reviewer) Limb, Susan, M.D. (Medical Team Leader) Chowdhury, Badrul A, M.D., Ph.D. (Medical Division Director)
Project Manager:	Jordan, Michelle

Keywords: Clinical Studies, NDA review,

1. EXECUTIVE SUMMARY

1.1 Conclusions and Recommendations

Nasonex® 50mcg [mometasone furoate nasal spray] (MFNS) is currently marketed for the prophylaxis and treatment of seasonal allergic rhinitis (SAR) in patients 2 years of age and older (NDA 20-762, approved on October 1, 1997) and treatment of nasal polyps (NDA 20-762/S023, approved on December 26, 2004). As part of the approval letter, the Agency stipulated that the applicant, Schering-Plough, conduct a study in patients 6-17 years of age with nasal polyps as a post-marketing commitment. Note that a partial waiver for this indication in children less than 6 years of age was granted. On March 3, 2005, the sponsor submitted a pediatric protocol (Study P04292) for nasal polyps.

The Agency submitted the following comments to the sponsor on (b) (4) following review of this protocol: (b) (4)

This supplement includes the complete study report of the pediatric nasal polyp clinical trial P04292 (b) (4) for the treatment of nasal polyps in pediatric patients aged 6-11 years (1 spray per nostril twice daily) and 12-17 years (2 sprays per nostril twice daily). This Phase 4 trial was primarily a safety study. Efficacy parameters were considered secondary and included change from baseline in bilateral polyp size, change from baseline in each patient-assessed diary symptom score, and the investigator's evaluation of therapeutic response. This sNDA submission did not contain electronic data sets for review by the Agency. However, upon preliminary survey of the information provided, electronic datasets will not be required for review at this time. Dr. Brian Porter reviewed the safety and efficacy of Study P04292 in detail. The reader is referred to Dr. Porter's review for information regarding the adequacy of Study P04292 (b) (4) indication in patients 6 - 17 years of age with nasal polyps. Because statistical tests were not needed in this study, therefore I did not conduct a formal statistical review.

-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
10/25/2010

JOAN K BUENCONSEJO
10/26/2010
I concur with Feng Zhou's review