

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/

Drug Name: Nasonex (mometasone furoate) Nasal Spray 50mcg

Indication(s): 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

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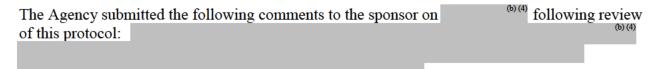
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Keywords: Clinical Studies, NDA review,

## 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.



This supplement includes the complete study report of the pediatric nasal polyp clinical trial P04292 (1) 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 in 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.

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/s/	
FENG ZHOU 10/25/2010	
JOAN K BUENCONSEJO 10/26/2010 I concur with Feng Zhou's review	

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