

MEDICAL OFFICER REVIEW

Division of Pulmonary, Allergy, and Rheumatology Products

Application #: NDA 20-762 Supplement 044	Application Type: NDA
Applicant: Schering-Plough	Proprietary Name: Nasonex
Investigator: N/A	USAN Name: Mometasone furoate
Category: Intranasal inhalation corticosteroid	Route of Administration: Intranasal inhalation
Reviewer: Brian Oscar Porter, M.D., Ph.D., M.P.H.	Review Date: January 12, 2011

SUBMISSIONS REVIEWED IN THIS DOCUMENT

Document Date	Submission Type	Comments
March 19, 2010	NDA 20-762 Supplement 044 SD-218	Labeling Supplement for pediatric nasal polyps
November 19, 2010	NDA 20-762 SD-233	Package Insert Draft re [redacted] (b) (4) for nasal congestion and pediatric nasal polyps
December 14, 2010	NDA 20-762 SD-239	Package Insert Draft re: pediatric nasal polyps
January 7, 2011	NDA 20-762 SD-242	Package Insert Draft re: pediatric nasal polyps
January 12, 2011	NDA 20-762 SD-244	Package Insert Draft re: pediatric nasal polyps

REVIEW SUMMARY: This is a medical officer review of a new labeling supplement for the addition of findings from a single pediatric clinical trial of Nasonex (mometasone furoate nasal spray; MFNS) intranasal inhalation corticosteroid spray in the treatment of nasal polyps in patients 6 to <18 years of age. Nasonex is approved for the treatment of seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR) in pediatric patients ≥ 12 years of age (October 1, 1997), 3 to 11 years of age (December 2, 1999), and 2 to < 3 years of age (July 17, 2002). Nasonex is also approved for the prophylaxis of SAR in patients ≥ 12 years of age (October 1, 1997), the treatment of nasal congestion associated with SAR in patients ≥ 2 years of age (May 26, 2010), and the treatment of nasal polyps in patients ≥ 18 years of age (December 15, 2004).

The following is a brief timeline of regulatory highlights for MFNS in the treatment of pediatric nasal polyps:

- **October 8, 2004:** Division granted a waiver to evaluate children < 6 years, given the low incidence of nasal polyps in children < 6 years, but a waiver was denied for children 6-17 years of age.
- **December 15, 2004:** MFNS approved for treatment of nasal polyps in patients ≥ 18 years of age with post-marketing commitment (PMC) to evaluate patients 6-17 years of age.
- **March 31, 2005:** Submission of protocol for proposed pediatric nasal polyp trial P04292.
- [redacted] (b) (4)
- **March 31, 2006:** Final protocol for P04292 submitted, incorporating Division recommendations.
- **April 9, 2009:** Division advised the Applicant to submit [redacted] (b) (4) for the purpose of including additional safety [redacted] (b) (4) information from trial P04292 in the label.

(b) (4)

On October 25, 2010, the Division [redacted] (b) (4) Labeling Supplement 044. The Applicant submitted product labeling (package insert and patient product information) on November 19, 2010, [redacted] (b) (4) incorporating the most recently approved indication for the relief of nasal congestion associated with SAR (approved May 26, 2010; Efficacy Supplement 038). The Division responded with labeling recommendations on December 9, 2010, [redacted] (b) (4). The Division also added the risk of glaucoma and cataracts to the Highlights: Warnings and Precautions section. The latter addition was intended to maintain consistency with the labeling of similar intranasal corticosteroid products and is a risk already described in Section 5, Warnings and Precautions of the Nasonex label.

(b) (4)

[redacted] Revised product labeling was submitted by the Applicant on January 7, 2011, to which the Division responded on January 10, 2011. Proposed labeling was discussed at the January 12, 2011, meeting of the Pediatric Review Committee (PeRC). Final labeling was submitted by the Applicant on January 12, 2011.

The final label includes the following paragraph that summarizes the results of clinical trial P02492 in Section 8.4, Pediatric Use:

The safety and effectiveness of Nasonex Nasal Spray for the treatment of nasal polyps in children less than 18 years of age have not been established. One 4-month trial was conducted to evaluate the safety and efficacy of Nasonex in the treatment of nasal polyps in pediatric patients 6 to 17 years of age. The primary objective of the study was to evaluate safety; efficacy parameters were collected as secondary endpoints. A total of 127 patients with nasal polyps were randomized to placebo or Nasonex Nasal Spray 100 mcg once or twice daily (patients 6 to 11 years of age) or 200 mcg once or twice daily (patients 12 to 17 years of age). The results of this trial did not support the efficacy of Nasonex Nasal Spray in the treatment of nasal polyps in pediatric patients. The adverse events reported in this trial were similar to the adverse events reported in patients 18 years of age and older with nasal polyps.

Upon clinical review, the proposed changes to the product label appear appropriate. The clinical review of NDA 20-762 [redacted] (b) (4) has previously concluded that the completion of trial P04292 satisfies the requirements of the PREA PMC for Nasonex in the treatment of pediatric nasal polyps (see Medical Officer Review by Dr. Brian Porter, dated November 18, 2010). No additional clinical issues have been identified. A copy of the revised Nasonex package insert is attached for reference.

The recommendation for this labeling supplement is Approval.

OUTSTANDING ISSUES: None

RECOMMENDED REGULATORY ACTION:

NDA, Efficacy/Label Supplement: Approval Not Approvable

Medical Reviewer: Brian Oscar Porter, M.D., Ph.D., M.P.H.

Medical Team Leader: Susan Limb, M.D.

11 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

BRIAN PORTER
01/12/2011

SUSAN L LIMB
01/12/2011