

510(K) SUMMARY**Contact Information**

Submitter's Name and Address: Hi-Tech Pharmacal, Inc.
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Name of Contact Person: Gary April
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Hi-Tech Pharmacal, Inc.

Date Summary was Prepared: December 30, 2013

Name of Device

Name of the Device: Nasal Ease Allergy Blocker
Trade or Proprietary Name: Nasal Ease Allergy Blocker
Common or Usual Name: Topical Nasal Cream -- Mechanical Allergen Particle Barrier
CFR Reference: 21 CFR 880.5045
Product Code: NUP
Regulatory Class: Class II

Predicate Devices

CODE	510(K)	MANUFACTURER	DEVICE
NUP	K053625	Turtech	NasalGuard Allergen Blocker
KCL	Preamendment	DeVilbiss	Model 175 Glass Powder Blower

Intended Use

Nasal Ease Allergy Blocker is intended to treat hay fever and allergy sufferers by promoting alleviation of mild allergic symptoms (i.e. mild nasal irritation including itchy, runny, or congested nasal passages) triggered by the inhalation of various airborne allergens including indoor and outdoor environmental pollens, house dust, animal hairs and dust mites.

Application of Nasal Ease produces a mucous-like gel barrier that evenly coats the nasal membranes and acts to block inhaled allergens within the nasal cavity.

Product Description

Nasal Ease Allergy Blocker is composed of 100% pharmaceutical grade Hydroxypropyl Methylcellulose (HPMC) which has been formulated into a micronized powder of fine particles of inert cellulose. Nasal Ease is administered by insufflation into the nose using a proprietary spray bottle which enables the powder to be applied evenly as a fine mist to the inside of the nasal cavity.

When Nasal Ease powder comes into contact with the moist surface of the nasal mucosa, it almost immediately forms a colorless, mucus-like fine gel which coats the inside of the nasal cavity. The inert gel acts as a mechanical barrier -- making it more difficult for inhaled allergens to come into contact with the skin in the nasal interior, and thus reducing the intensity of allergic rhinitis symptoms.

One bottle squeeze releases around 3.2mg of powder. The maximum usual dose is around 3 puffs/day into each nostril, giving a total of 19mg/day.

The cellulose gel is considered inert and does not penetrate the dermal layer of the skin. On average, protection lasts for 4-6 hours before the gel has to be reapplied. Nasal Ease is intended for topical use and provided non-sterile.

Comparison to Predicate

PARAMETER	Nasal Ease Allergy Blocker	NasalGuard Allergen Blocker
DESCRIPTION	HPMC Powder	Glycerin-Based Gel
COMPOSITION	100% pharmaceutical grade Hydroxypropyl Methylcellulose (HPMC) which has been formulated into a micronized powder of fine particles of inert cellulose.	Water-based gel that contains cosmetic grade ingredients that are commonly found in commonly used lotions, creams, gels and other conditioners for the hair and skin.
APPLICATION	Administered by insufflation into the nose by spray bottle which enables powder to be applied evenly as a fine mist to the inside of the nasal cavity.	Nasal ointment is applied by finger or cotton swab to the outside of the nasal passages, around the nostrils and upper lip.
MODE OF ACTION	When Nasal Ease powder comes into contact with the moist surface of the nasal mucosa, it almost immediately forms a colorless, mucus-like fine gel which coats the inside of the nasal cavity -- acting as a mechanical barrier.	Utilizes a patented methodology that uses the cationic properties of its ingredients to create an electrostatic filter that filters airborne allergens before they enter the nasal passages.

Particle Size Distribution

Particle size distribution has been analytically characterized with 99.4% of particles in the 5-500 micron (μm) diameter range and a mean particle size of 118 μm .

Particle Deposition -- It is well recognized that nasally inhaled particles are deposited in the respiratory tract according to size. Particles larger than 5 μm are deposited in the nasopharynx, whereas particles ranging in size from 1-5 μm are typically deposited in the trachea, bronchial, and bronchiolar region. Only particles typically $\leq 1 \mu\text{m}$ in diameter are observed in the alveoli.

For Nasal Ease, no particles $< 1.9 \mu\text{m}$ were detected. The results of this particle size distribution analysis provide evidence that essentially none of the HPMC reach the alveoli and that the whole quantity can be considered as swallowed (as described below).

Mucociliary Clearance -- Particles deposited in the nose and in the tracheo-bronchial airway are trapped in the mucous lining. The inert particles eventually travel with the downward mucous flow into the pharynx where they are swallowed and end up in the gut.

Safety Testing & Toxicology

HPMC is recognized in the EU as a food additive and as GRAS by the FDA. Patty's Industrial Hygiene and Toxicology describes the cellulose ethers (including HPMC) as "all very low in toxicity" and "exposure of humans to the dust in manufacturing operations over many years has not led to any known adverse effects".

Feeding experiments in rats, dogs, and also human volunteers showed a lack of toxic effect. Studies in volunteers revealed no serious adverse effects of taking the material as a snuff for several weeks.

No studies of genotoxicity, or reproductive toxicity have been identified, but the chemistry of the materials, their recognized safety in food use, and lack of toxicity in feeding studies suggest that further studies are not necessary.

Overall, HPMC is a remarkably safe material when given orally in gram quantities. The quantity, grade, and route of administration of HPMC used in Nasal Ease do not present any serious toxicological risks.

Biocompatibility

Biocompatibility testing included cytotoxicity, sensitization, and irritation. The results demonstrated that there are no biocompatibility concerns with Nasal Ease.

Stability and Shelf Life

Stability and shelf life testing results support a shelf life of at least 3 yrs at 40°C. Once the bottle is opened, labeling directs the consumer to use the product within 6 months.

In Vitro Studies

Several in vitro studies have been performed using a simulated barrier model to investigate and characterize the performance of Nasal Ease compared to several controls. The results of these studies validate in principle that significant delay of allergen entry into the mucosa could be beneficial to hay fever sufferers through the reduction of allergen exposure.

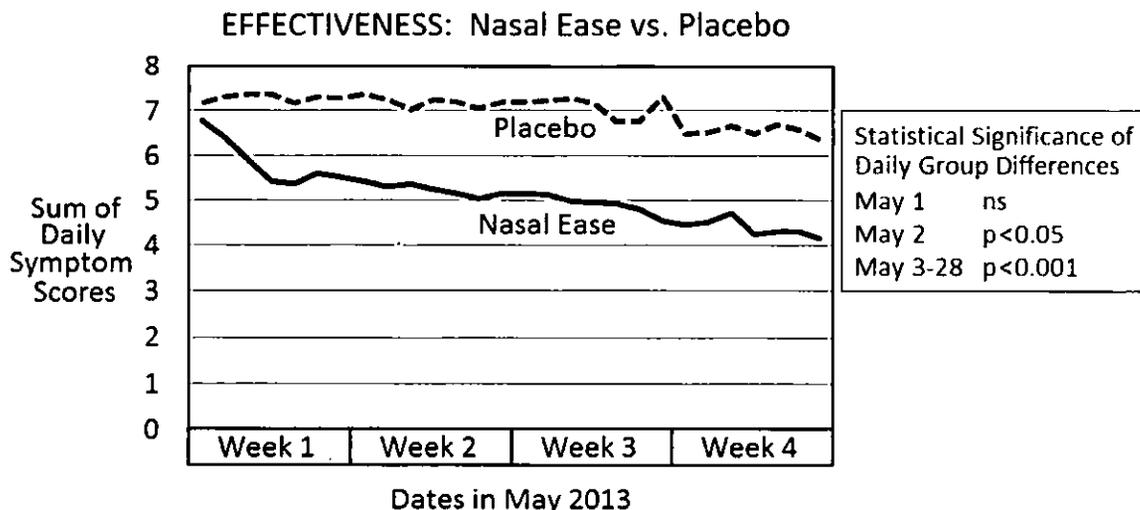
In addition, an in vitro study was performed directly comparing the allergen blocking capability of Nasal Ease to the predicate, NasalGuard. The study results demonstrate that Nasal Ease and NasalGuard significantly reduce the diffusion of pollen allergen in vitro for up to 6 hours.

Clinical Study

Nasal Ease Allergy Blocker was demonstrated to significantly reduce symptoms of allergic rhinitis in a prospective, randomized, placebo-controlled clinical validation study. Patients with mild symptoms of seasonal allergic rhinitis to grass pollen self-administered either Nasal Ease or placebo (lactose powder with same particle size and appearance as Nasal Ease).

Over the course of 4 weeks during allergy season, 53 placebo patients and 54 active patients recorded their daily symptom scores including trouble with sneezing, running nose, stuffy nose, eye symptoms and lower airway symptoms. Short Message Service (SMS) on mobile phones was used for reminders of treatment times.

The study showed significant reductions of severity scores for sneezing, running and stuffy nose, and symptoms from eyes and lower airways -- both separately and together (all $p < 0.001$). Reflective opinion of effect and guess on treatment at follow-up visits (both $p < 0.001$) confirmed effectiveness. No clinically significant adverse effects were observed.



The figure on the previous page and the tables below summarize the effectiveness results from the clinical validation study.

SCORE	SYMPTOMS SEVERITY
1	No Trouble At All
2	Little Trouble
3	Moderate Trouble

SCORE	SYMPTOMS SEVERITY
4	Rather Much Trouble
5	Much Trouble
6	Very Much Trouble

EFFECTIVENESS RESULTS -- MEAN SYMPTOM SCORES		
SYMPTOM ASSESSMENT	ACTIVE / N=54	PLACEBO / N=53
Sneezing	1.65	2.31
Running Nose	1.75	2.37
Stuffy Nose	1.76	2.32
Eye Symptoms	1.59	2.18
Lower Airways	1.44	1.92
Sum of Nasal Symptoms	5.16	6.99
Sum of All Symptoms	8.19	11.1

Clinical Summary -- In a randomized placebo-controlled clinical validation study of >100 seasonal allergic rhinitis patients, Nasal Ease was demonstrated to provide significant protection against all SAR symptoms from both upper and lower airways during the grass pollen season in an adult population. The magnitude and scope of efficacy support the use of the product as an early choice in the treatment of allergic rhinitis.

Study Limitations -- included a lack of evaluation in subjects with severe symptoms; and lack of pollen counts measurements during the study.

History of Safe and Effective Use

Nasaleze has been registered as a Class I Medical Device with MHRA since 1991 and is currently sold in more than 50 countries worldwide

During this +20 year period, there have been no reports of any serious adverse events attributed to Nasaleze by consumers who have safely used over 7,000,000 products sold.

Conclusions

By virtue of its physical characteristics, intended use, and performance testing, Nasal Ease is equivalent to products legally cleared to be marketed in the US, specifically NasalGuard.

Nasal Ease poses no safety risk to users, and has been shown to significantly block allergen entry into the nasal mucosa. Clinical studies have demonstrated that Nasal Ease's mucous-like gel barrier is beneficial to hay fever sufferers through the reduction of nasal allergen exposure and consequently a reduction in symptoms from seasonal allergic rhinitis.



December 31, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Hi-Tech Pharmacal, Inc
% Gary April, President, Healthcare
Products Division, Hi-Tech Pharmacal, Inc.
369 Bayview Avenue
Amityville, NY 11701

Re: K132520

Trade/Device Name: Nasal Ease Allergen Blocker
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical recirculating air cleaner
Regulatory Class: Class II
Product Code: NUP
Dated: November 26, 2013
Received: November 27, 2013

Dear Mr. April:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Bradley S. Cunningham -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Device Name: Nasal Ease Allergy Blocker

510(k) Number: K132520

Indications for Use: Nasal Ease Allergy Blocker is intended to treat hay fever and allergy sufferers by promoting alleviation of mild allergic symptoms (i.e. mild nasal irritation including itchy, runny, or congested nasal passages) triggered by the inhalation of various airborne allergens including indoor and outdoor environmental pollens, house dust, animal hairs and dust mites.

Application of Nasal Ease produces a mucous-like gel barrier that evenly coats the nasal membranes and acts to block inhaled allergens within the nasal cavity.

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CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION

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Prescription Use OR Over-The-Counter Use

(Per 21 CFR 801.109)