K053625

FEB 2 2 2006

16.0 510(k) Summary

Name of Device

Trade Name: NasalGuard Allergen Blocker Gel
Common Name: NasalGuard
Classification Name: Unclassified

Predicate Device

510(K)	Manufacturer	Device	Approval Date
K042610	Dr. Theiss Naturwaren Gmbh, Germany	Dr.Theiss Alergol Pollen Blocker Cream	05/16/2005

Device Description

NasalGuard is a water-based gel consisting of common, GRAS cosmetic grade ingredients. The product is applied by finger or cotton swab to the outside of the nasal passages, around the nostrils and upper lip. NasalGuard 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.

The gel is considered innocuous 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. NasalGuard is intended for topical use and provided non-sterile.

Intended Use

NasalGuard® is intended to promote alleviation of mild allergic symptoms (i.e. mild nasal irritation including itchy, runny or congested nasal passages) triggered by the inhalation of various allergens including environmental pollens, house dust, animal hairs and dust mites.

Pharmaceutical and Physical Characteristics

NasalGuard (7g nasal ointment) is a 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.

Safety Testing

By using a water-based gel that contains only GRAS cosmetic grade ingredients, NasalGuard is maintained as an innocuous and safe product. There have been no reports of any serious adverse effects resulting from its use by over 20,000 users.

Laboratory Testing

Leberco Testing Inc. has tested NasalGuard for primary dermal irritation, primary eye irritation, gingival irritation and acute oral toxicity. The findings indicate NasalGuard as innocuous from toxicological standards. NasalGuard poses no health risks or adverse side effects. NasalGuard is intended for topical use and provided non-sterile.

Summary of Clinical Results

A double blind, crossover study of 43 subjects with known allergic rhinitis condition was conducted in May 2000. The use of NasalGuard showed significant efficacy during the trial in reducing allergic rhinitis symptoms compared with an active control.

These test data has been statistically analyzed as per the Alergol clinical study criteria.

The chi-square test has p-value = 0.7974, which indicates that no statistically significant difference exists between these two treatments. However, the results indicate a somewhat more efficacious trend for the NasalGuard compared with Alergol.

The comparative responses of the patients are classified as follows:

Patient Percentage	**Device**	
	NasalGuard	**Alergol**
High Responders	56%	51%
Responders	23%	24%
Non-Responders	21%	25%
High Responders & Responders Combined	**79%**	**75%**

Proof of Substantial Equivalency of NasalGuard to Alergol

The Predicate device Alergol data is used as a control and Statistical Analysis of the data proves that NasalGuard is equally efficient as the predicate device in reducing the symptoms of Allergic Rhinitis.

The Asthma Center conducted a Mold and Pollen Spore counting bench test comparing the pollen capturing capacity of NasalGuard, Alergol with Silicon gel. Test results indicated both NasalGuard and Alergol on average captured mold spores approximately **three times more** than the control, Silicon Gel.

Conclusions:

By virtue of its physical characteristics and intended use, the NasalGuard Allergy Blocker Gel is substantially equivalent to devices legally cleared to be marketed in the United States; specifically Alergol.

NasalGuard poses no safety threat to users and has been demonstrated to attract airborne allergens and work as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2006

Denison Pharmaceuticals, Inc.
c/o Mr. Ashok L. Wahi
Trutek Corporation
80 West End Ave.
Somerville, NJ 08876

Re: K053625
Trade/Device Name: NasalGuard®
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical recirculating air cleaner
Regulatory Class: Class II
Product Code: NUP
Dated: December 22, 2005
Received: December 29, 2005

Dear Mr. Wahi:

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.

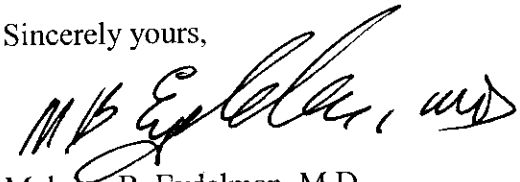
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

13.0 Indications for Use Statement

Device Name: NasalGuard

510(k) Number: K053625

Indications for Use:

NasalGuard® is intended to promote alleviation of mild allergic symptoms (i.e. mild nasal irritation including itchy, runny or congested nasal passages) triggered by the inhalation of various allergens including environmental pollens, house dust, animal hairs and dust mites.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109)

OR

Over-The-Counter-Use ✓ (Optional format)

Karen A Baker

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K053625