July 28, 2021

Nasaleze International Ltd
Matt Duxbury
Export Director, Nunnery Mills
Old Castletown Road
Douglas, Isle of Man, IM2 1QA
British Isles

Re: K170848
Trade/Device Name: Alzair Allergy Blocker
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical recirculating air cleaner
Regulatory Class: Class II
Product Code: NUP

Dear Matt Duxbury:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 14, 2017. Specifically, FDA is updating this SE Letter because the signature was omitted from the original letter, as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shu-Chen Peng, Ph.D., OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-6481, Shu-Chen.Peng@fda.hhs.gov.

Sincerely,

Srinivas Nandkumar -S

Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

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

June 14, 2017

Nasaleze International Ltd
Mr. Matt Duxbury
Export Director, Nunnery Mills
Old Castletown Road
Douglas, Isle of Man, IM2 1QA
British Isles

Re: K170848
Trade/Device Name: Alzair Allergy Blocker
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: Class II
Product Code: NUP
Dated: March 15, 2017
Received: March 21, 2017

Dear Mr. Duxbury:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K170848

Device Name
Alzair Allergy Blocker

Indications for Use *(Describe)*
Alzair 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 airbone 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(K) SUMMARY

### *Contact Information*


| | |
|---|---|
| Submitter's Name and Address: | Nasaleze International Ltd<br>Nunnery Mills, Old Castletown Road<br>Douglas, Isle of Man, IM2 1QA, British Isles<br>TEL + 44 (0) 1624 611 050 |
| Name of Contact Person: | Matt Duxbury<br>Export Director<br>Nasaleze International Ltd. |


Date Summary was Prepared: May 18, 2017

### *Name of Device*

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

### *Predicate Device*

K132520 -- Allergy Blocker, Nasal Eze International (31-DEC-14)

### *Basis for Submission*

The changes to the product are the addition of the Prescription Use identifier in the labeling and the new brand for US marketing, “Alzair Allergy Blocker”.

### *Product Description*

Alzair Allergy Blocker is composed of pharmaceutical grade Hydroxypropyl Methylcellulose (HPMC; 98.5%) and high quality peppermint (1.5%) which has been formulated into a micronized powder of fine particles of inert cellulose. Alzair Allergy Blocker 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 Alzair Allergy Blocker 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.

### *Indications for Use*

Alzair 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 Alzair Allergy Blocker produces a mucous-like gel barrier that evenly coats the nasal membranes and acts to block inhaled allergens within the nasal cavity.

### *Comparison to Predicate*

| | PREDICATE DEVICE | ADD-TO-FILE DEVICE | SUBJECT DEVICE |
|---|---|---|---|
| 510(K) | K132520 | N/A | K170848 |
| PRODUCT | Allergy Blocker | Allergy Blocker (with Mint) | Alzair Allergy Blocker |
| **INGREDIENTS** | **HPMC Powder 100%** | **HPMC Powder 98.5%**<br>**Peppermint Powder 1.5%** | **SAME** |
| INDICATIONS | See previous page. | | SAME |
| **PRESCRIPTION DESIGNATION** | **OVER-THE-COUNTER USE** | | **PRESCRIPTION USE** |
| PRODUCT CODE | NUP | | SAME |
| REGULATION | 880.5045 | | SAME |
| DATE CLEARED | 12-31-14 | Letter to file 04-02-15 | PENDING |

### *Safety Testing & Toxicology*

HPMC and spearmint are recognized as GRAS in the US. Overall, HPMC is a remarkably safe material when given orally in gram quantities. The quantity, grade, and route of administration of HPMC used in Alzair Allergy Blocker do not present any serious toxicological risks.

Combining HPMC with Mint flavoring is most unlikely to cause any toxicological hazards as all the ingredients are rated non-hazardous and the quantities ingested are well below any known recommended unconditional daily acceptance level.

### *Biocompatibility*

Biocompatibility testing included cytotoxicity, sensitization, and irritation. The results demonstrated that there are no biocompatibility concerns with Alzair Allergy Blocker.

### *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.

### *History of Safe and Effective Use*

The predicate, Nasaleze Allergy Blocker (which has an identical formulation), 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 +25 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, Alzair Allergy Blocker (K170848) is equivalent to Nasaleze Allergy Blocker (K132520).

Alzair Allergy Blocker poses no safety risk to users, and has been shown to significantly block allergen entry into the nasal mucosa. Clinical studies have demonstrated that the allergy blocker'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.