DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS AND BIOLOGICS FOR HUMAN USE

1. Date Submitted: 06/16/2015

2. Label Review Number (Biologics):

3. NDA/ANDA/AADA or BLA/PMA
Type: NDA Number: 202236
☒ Single product ☐ Multiple products
For multiple products, submit completed form and specimen of advertising/promotional materials to one application of choice, and attach separate sheet addressing items 3-5 for remainder of products. Refer to No. 3 on instruction sheet.

NOTE: Form FDA 2253 is required by law. Reports are required for approved NDAs and ANDAs (21 CFR 314.81).

4. Proprietary Name: DYMISTA

5. Established Name: azelastine hydrochloride and fluticasone propionate
Product Code No.:

6. Package Insert Date and ID Number (Latest final printed labeling): IN-023A6-05 02/2015

7. Manufacturer Name: MEDA Pharmaceuticals Inc.
License No. (Biologics):

8. **Advertisement / Promotional Labeling Materials**

a. **Please check only one:** ☒ Professional ☐ Consumer

Material Type (use FDA codes) b.	Dissemination/ Publication Date c.	Material ID Code d.	Material Description e.
Sales Aid	07/06/2015	US/DYM/0415/0054	2015 Fall CVA
Sales Aid	07/06/2015	US/DYM/0415/0054a(1)	2015 Fall CVA New Indication Violator

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To delete a row, click the "Delete Row" button for that row (or press the enter key if you've tabbed into the button). You cannot delete the last remaining row. Add New Row

f. Comments

NOTE: US/DYM/0415/0054a(1), 2015 Fall CVA New Indication Violator to be used for 6 months only.

COPY

9. Applicant's (or Agent's) Return Address
Address 1 *(Street address, P.O. box, company name c/o)*: Meda Pharmaceuticals Inc.
Address 2 *(Apartment, suite, unit, building, floor, etc.)*: 265 Davidson Avenue
City: Somerset
State/Province/Region: New Jersey
Country: USA
ZIP or Postal Code: 08873-4120

10. Responsible Official's (or Agent's)
a. Telephone Number *(Include area code)*: 732-564-2284
b. FAX Number *(Include area code)*: 732-564-2377
c. Email Address: lorna-jane.bremer@meda.us

PLAINTIFFS' TRIAL EXHIBIT

HIGHLY CONFIDENTIAL

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11. Typed Name and Title of Responsible Official or Agent	12. Signature of Responsible Official or Agent	13. Date
Lorna-Jane Bremer, Senior Director Regulatory Affairs	Sign	06/16/2015

14. For CBER Products Only *(Check one)*

☐ Draft ☐ Final

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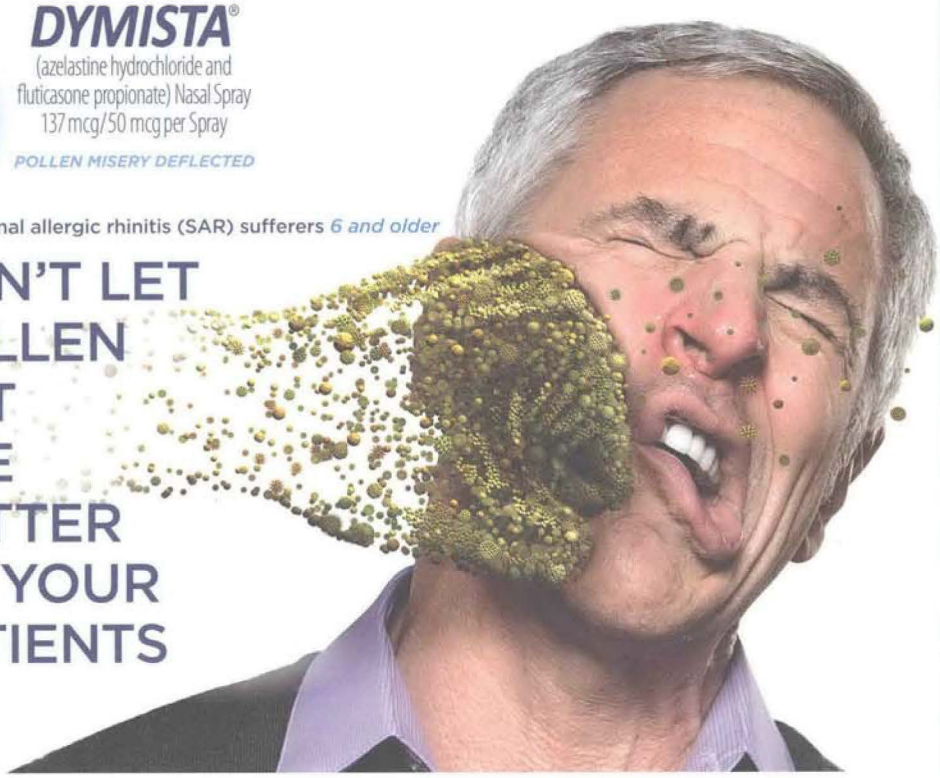
DYMISTA®

(azelastine hydrochloride and fluticasone propionate) Nasal Spray 137 mcg/50 mcg per Spray

POLLEN MISERY DEFLECTED

For seasonal allergic rhinitis (SAR) sufferers *6 and older*

DON'T LET POLLEN GET THE BETTER OF YOUR PATIENTS



Only Dymista offers fast relief[a] *and* inflammation control—with every dose[1,2]

[a]As demonstrated in patients 12 and older, fast relief is defined as the first timepoint (30 minutes) at which Dymista was significantly superior to placebo in the mean change from baseline in instantaneous total nasal symptom score (iTNSS) and was sustained thereafter.[1]

Indications

DYMISTA contains an H1-receptor antagonist and a corticosteroid, and is indicated for the relief of symptoms of seasonal allergic rhinitis in patients 6 years of age and older who require treatment with both azelastine hydrochloride and fluticasone propionate for symptomatic relief.

Important Safety Information

- Somnolence: Avoid engaging in hazardous occupations requiring complete mental alertness such as driving or operating machinery when taking DYMISTA.
- Avoid concurrent use of alcohol or other central nervous system (CNS) depressants with DYMISTA because further decreased alertness and impairment of CNS performance may occur.
- Epistaxis, nasal ulcerations, nasal septal perforation, impaired wound healing, *Candida albicans* infection: Monitor patients periodically for signs of adverse effects on the nasal mucosa. Avoid use in patients with recent nasal ulcers, nasal surgery, or nasal trauma.

Please see additional Important Safety Information throughout and Full Prescribing Information in pocket.

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3 pivotal clinical studies of total nasal symptom scores showed

RAPID RELIEF

BECAUSE PATIENTS HAVE WAITED LONG ENOUGH

Onset of nasal symptom relief as fast as **30 minutes**[1] **vs placebo** (*P*<.05)

Onset was defined as the first timepoint at which Dymista was significantly superior to placebo in the mean change from baseline in iTNSS and was sustained thereafter in patients ≥12[1,a]

▶ In an independent survey, 85% of patients identified rapid relief of symptoms as one of the most important attributes of allergic rhinitis treatment[3]

[a] TNSS is calculated as the sum of the patients' scoring of the 4 individual nasal symptoms (rhinorrhea, congestion, sneezing, and itching) on a 0 to 3 categorical severity scale (0=absent, 1=mild, 2=moderate, 3=severe).[1]

Important Safety Information continued

- Glaucoma or posterior subcapsular cataracts: Monitor patients closely with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.
- Potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. More serious or even fatal course of chickenpox or measles in susceptible patients. Use caution in patients with the above because of the potential for worsening of these infections.
- Hypercorticism and adrenal suppression with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue DYMISTA slowly.

Please see additional Important Safety Information throughout and Full Prescribing Information in pocket.

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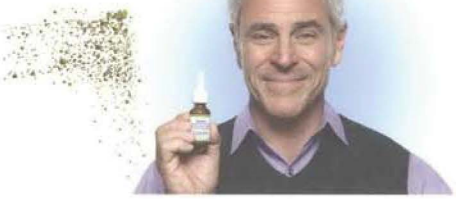


DYMISTA®
(azelastine hydrochloride and fluticasone propionate) Nasal Spray
137 mcg/50 mcg per Spray

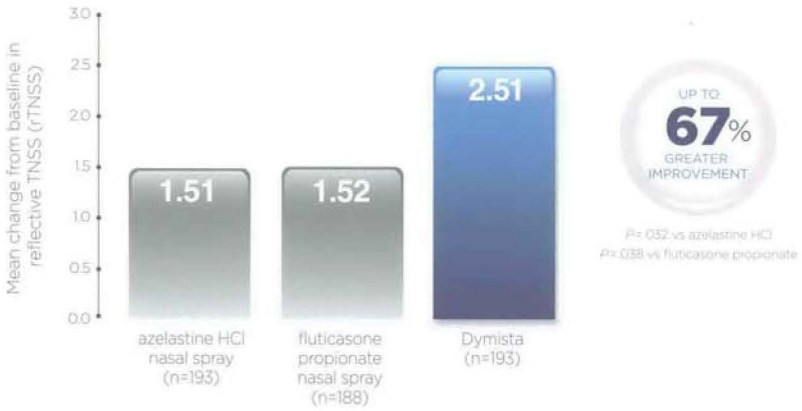
POLLEN MISERY DEFLECTED

SUPERIOR EFFICACY

VS AZELASTINE HCL OR FLUTICASONE PROPIONATE COMPARATORS

Dymista demonstrated significantly greater improvement in reflective total nasal symptom relief in patients ≥12[1,4]

MAGNITUDE OF NASAL SYMPTOM RELIEF



Data shown are from pivotal study MP 4004. Across all 3 pivotal clinical trials, Dymista provided a significant improvement in rTNSS with Dymista, ranging from 43% to 67% relative to azelastine HCl or fluticasone propionate comparators, as presented in the Full Prescribing Information.[1,4]

Change from baseline in the placebo-subtracted mean rTNSS for each day (maximum score 24), averaged over the 14-day study period. Percent difference represents the improvement in rTNSS with Dymista relative to azelastine HCl or fluticasone propionate comparators. **The azelastine HCl and fluticasone propionate comparators were delivered via the same device and vehicle as Dymista and are not commercially available.[1,4]**

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