

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 06/17/2015	3. NDA/ANDA/AADA or BLA/PMA Type: NDA Number: 202236 <input checked="" type="checkbox"/> Single product <input type="checkbox"/> 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.
	2. Label Review Number (Biologics)	

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.	
www-banner	06/22/2015	US/DYM/0515/0073	Competitive vs Flonase Banner: 300 x 250	Delete Row

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f. Comments

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	
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11. Typed Name and Title of Responsible Official or Agent Lorna-Jane Bremer, Senior Director Regulatory Affairs	12. Signature of Responsible Official or Agent Sign	13. Date 06/17/2015
14. For CBER Products Only (Check one) <input type="checkbox"/> Draft <input type="checkbox"/> Final		



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(astemizole hydrochloride) as
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