



NDA 21-231/S-009

**NDA APPROVAL**

AstraZeneca Pharmaceuticals, LP  
Attention: Laura E. Garcia-Davenport,  
Director Regulatory Affairs  
1800 Concord Pike  
PO Box 8355  
Wilmington, DE 19803-8355

Dear Ms Garcia-Davenport:

Please refer to your New Drug Application (NDA) dated July 21, 2006, received July 22, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zomig (zolmitriptan) Orally Disintegrating Tablets.

We also acknowledge receipt of your amendment dated March 13, 2007.

This "Changes Being Effected" supplemental new drug application was submitted in response to an Agency Letter dated May 25, 2006 and provides information about Selective Serotonin Reuptake Inhibitors/Serotonin Norepinephrine Reuptake Inhibitors and Serotonin Syndrome.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert, text for the patient package insert,). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an

action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

If you have any questions, contact Lana Chen, Regulatory Project Manager, at (301) 796-1056.

Sincerely,

*{See appended electronic signature page}*

Russell Katz, M.D.  
Division Director  
Division of Neurology Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

ENCLOSURE:  
Content of Labeling

Application  
Type/Number

Submission  
Type/Number

Submitter Name

Product Name

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NDA-21231

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SUPPL-9

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ASTRAZENECA  
PHARMACEUTICA  
LS LP

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ZOMIG (ZOLMITRIPTAN)  
ORALLY DISIN.TABS.

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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RUSSELL G KATZ

08/11/2010