August 21, 2013

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

2013 AUG 22 A 9:56

RE: Citizen Petition

The undersigned submits this petition under 10.30 of the Code of Federal Regulations Title 21 to request the Commissioner of Food and Drugs to take administrative action.

A. Action requested

An NDA application for Rizatriptan Oral Film is currently under review by the Division of Neurology Products (NDA 205-394). The PDUFA goal date is set to February 3, 2013.

The petitioner requests the Commissioner to designate the Rizatriptan Oral Film, when approved pursuant to section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, as AB relative to the Reference Listed Drug (RLD), Maxalt-MLT® (Merck, NDA 20-865).

B. Statement of grounds

The petitioner respectfully believes the Rizatriptan Oral Film meets FDA's criteria for a therapeutic equivalent drug product.

There are several factors to support the request for the Rizatriptan Oral Film to be designated as AB relative to the RLD, Maxalt-MLT® orally disintegrating tablet including the following:

1. The active drug, rizatriptan benzoate, in the Rizatriptan Oral Film and the RLD has been previously approved by FDA as safe and effective. Furthermore, based on the biopharmaceutical classification system, rizatriptan benzoate is considered a class one drug, i.e. it has a high solubility, high permeability, and the absorption of the drug is not affected by the presence of food. Product development data show the dissolution of rizatriptan in a variety of dissolution media and dissolution test conditions is very rapid and essentially independent of both particle sizing and dosage form.

2. The Rizatriptan Oral Film and the RLD are effectively pharmaceutical equivalents in that:

(a) they contain identical amounts of the same active drug ingredient, which in both the Rizatriptan Oral Film and the RLD is a 5mg strength and a 10mg strength of rizatriptan;

(b) they are very similar in their performance as dosage forms;

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(c) they have the same oral route of administration, with both products being placed on the tongue where they rapidly disintegrate; and

(d) both meet compendial or other applicable standards of strength, quality, purity, and identity.

The petitioner respectfully suggests that the Rizatriptan Oral Film is pharmaceutically equivalent and not a pharmaceutical alternative to the RLD. Unlike, for example, tablets and capsules where an extra shell is present and could have an impact, the main pharmaceutical difference between the Rizatriptan Oral Film and the RLD are that of shape, dimension and excipients. The Rizatriptan Oral Film can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling as the RLD. Hence, the petitioner respectfully suggests that the Rizatriptan Oral Film conforms to FDA's criteria for pharmaceutical equivalence.

3. The Rizatriptan Oral Film is bioequivalent to the RLD, and does not present a known or potential bioequivalence problem, and meets an acceptable *in vitro* standard. The data from the pivotal bioequivalency study clearly demonstrate that the Rizatriptan Oral Film products has a bioequivalent plasma profile to the RLD, and thus, the Rizatriptan Oral Film can be substituted for the RLD without a concern for efficacy by the patient.

4. The Rizatriptan Oral Film will be adequately labeled. The packaging of the Rizatriptan Oral Film will be very similar to that of the RLD. Each Rizatriptan Oral Film will be individually packed in a laminated foil for single use, and then several single units will be packaged in a box. This is similar to the RLD, with the exception that the individual units of the RLD are blister packed and then boxed.
The administration procedure is equivalent for both the Rizatriptan Oral Film and the RLD products. The instructions listed in the patient information document for Maxalt-MLT® are:

- Remove the blister from the foil pouch. Do not push the MAXALT-MLT® orally disintegrating tablet through the blister.
- Peel open the blister pack with dry hands and place the MAXALT-MLT® orally disintegrating tablet on your tongue. The tablet will dissolve and be swallowed with your saliva. No liquid is needed to take the orally disintegrating tablet.

Essentially identical instructions will be provided in the patient information document for the Rizatriptan Oral Film with the exception of the blister since the film is readily available from the pouch. The likelihood of confusion by the patient is extremely limited.

The behavior of the Rizatriptan Oral Film and the RLD in the mouth share multiple similarities: both products are first placed on the tongue; once placed in the tongue both products rapidly disintegrate; concurrent with the disintegration, both products will be swallowed with saliva without the need of any liquid.

5. The Rizatriptan Oral Film will be manufactured in compliance with Current Good Manufacturing Practice regulations.

The petitioner respectfully believes that the Rizatriptan Oral Film can be classified as therapeutically equivalent and can be substituted for the RLD with the full expectation that the Rizatriptan Oral Film will produce the same clinical effect and safety profile as the prescribed reference listed drug product.

C. Environmental impact

The undersigned claims for categorical exclusion under 21 CFR 25.30(h).

D. Economic impact

Not applicable as of yet.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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