

MonoSol Rx, LLC



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Monday, July 31, 2006

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

Citizen Petition

The undersigned submits this petition, in quadruplicate, pursuant to Section 505(j)(2)(C) of the Federal Food Drug and Cosmetic Act and in accordance with 21 CFR 10.30 requesting the Commissioner of Food and Drug to declare that the drug product, Loperamide Hydrochloride Orally Dissolving Strips 2 mg, is suitable for consideration in an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner declare that Loperamide Hydrochloride Orally Dissolving Strips 2 mg is suitable for submission as an ANDA. The reference listed drug (RLD) product upon which this petition is based is Imodium (loperamide hydrochloride) Tablets, 2 mg (NDA 19-860 held by McNeil). The RLD product is approved for marketing as an over-the-counter (OTC) drug product. A copy of the appropriate page from the electronic Orange Book, *Approved Drug Products with Therapeutic Equivalence Evaluations* edition, accessed on July 31, 2006 that lists the approval is provided in Attachment A. The petitioner seeks a change in the dosage form, from a tablet to an orally dissolving strip, from that of the RLD product.

B. Statement of Grounds

The RLD product, Imodium Tablets, is currently available in a 2 mg tablet dosage form and is approved for OTC marketing. The proposed drug product is consistent with the currently approved RLD product's labeling with the exception of the dosage form and directions for administration (because of the difference in dosage form). Although we are not aware of any FDA approved drug products presently marketed in an orally dissolving strip dosage form, there are a number of products that are marketed over-the-counter that utilize this dissolving film technology. For instance, a number of OTC products are marketed using this technology. The proposed dosage form will contain inactive ingredients that are generally recognized as safe (GRAS) or have been approved in other marketed approved drug products. The orally dissolving strip is designed to be placed on the tongue and will dissolve within a few seconds after contact. This proposed dosage

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form is directly analogous to the fast dissolving and disintegrating tablets that have been approved by the agency. Each dosage unit (strip) will contain 2 mg of loperamide hydrochloride and the petitioner will demonstrate bioequivalence to the RLD. In addition the FDA has approved at least one petition permitting the submission of an ANDA for an orally dissolving film strip (Docket # 2004P-0353 approved July 5, 2005).

The proposed product will provide an alternate dosage form that may prove to be more convenient for patients who have difficulty swallowing a tablet or do not have access to water when a dose is needed. The proposed product will be labeled in accordance with the approved labeling of the RLD product upon which this petition is based. Any difference in the labeling will relate only to the difference in dosage form and the method of administration (dissolving the strip on the tongue as opposed to chewing and swallowing the tablet) and those differences that may be necessary because the products are made by different manufacturers or because of patent or exclusivity protections.

Copies of the labeling of the RLD product upon which this petition is based and draft labeling for the proposed product are included in Attachments B and C, respectively. The proposed labeling is the same as the approved RLD product labeling, including doses recommended, indications and conditions of use, with the exceptions identified above.

The petitioner requests that the Commissioner find that a change in dosage form from a tablet to an orally dissolving strip raises no questions of safety or effectiveness.

Pediatric Waiver Request

In December of 2003, Congress passed the Pediatric Research Equity Act of 2003 that amended the Federal Food, Drug, and Cosmetic Act to provide the Agency authority to require drug firms to study drugs in pediatric patients, if the Agency concludes that such study would provide beneficial health data for that patient population. The Act specifically requires that a request for a new dosage form is subject to a pediatric evaluation. The act also provides for a waiver from such requirement if the drug:

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(II) is not likely to be used in a substantial number of pediatric patients.

MonoSol Rx hereby requests that a waiver from the conduct of pediatric studies be granted for the approval of this petition to permit subsequent ANDA filing.

The reference listed drug product that is the subject of this petition is an immediate release tablet. There are however other FDA approved products for the same active ingredient in liquid as well as chewable tablets dosage forms. The array of FDA approved loperamide hydrochloride products (e.g., tablet, chewable tablet and liquid) contain labeling providing for appropriate dosing for pediatric patients for whom these products are indicated. Loperamide, a product first approved for OTC use in 1988, is not

on the list of drug products for which additional pediatric information may produce health benefits in the pediatric population (May 2001) and since it is already appropriately labeled for pediatric patients, the introduction of an alternate dosage form that can be used in a similar manner as the other approved loperamide hydrochloride products will not represent a meaningful therapeutic benefit over existing therapies for pediatric patients. Based on the nature of the medication and its routine use it is not likely that the product will be used in a substantial number of pediatric patients other than those for whom it is already appropriately labeled.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

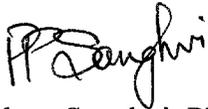
D. Economic Impact

The petitioner believes that this is not applicable in this case, but agrees to provide such an analysis if requested by the Agency.

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 includes representative data and information known to the petitioners, which are unfavorable to the petition.

Respectfully submitted,



Pradeep Sanghvi, Ph.D.
Vice President, Pharmaceutical Development

Attachments: A-C

cc: Leo Zadecky
cc: Cecelia Parise