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VIA REGULATION.GOV

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

ANDA SUITABILITY PETITION

Dear Sir/Madam:

The undersigned submits this petition under Sections 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FDCA, or the "Act") and 21 CFR § 314.93 to request that the Commissioner of Food and Drugs determine that an Abbreviated New Drug Application (ANDA) may be submitted for a drug product that is not identical to the Reference Listed Drug (RLD) for esomeprazole magnesium delayed-release capsules.

A. Action Requested

The Petitioner seeks a determination from the Commissioner of Food and Drugs that an ANDA may be submitted for esomeprazole delayed-release capsules, 2.5 mg, 5 mg, and 10 mg strengths.

B. Statement of Grounds

Our client is requesting to file an ANDA for esomeprazole magnesium delayed-release capsules in 2.5 mg, 5 mg, and 10 mg strengths. The RLD product, Nexium (esomeprazole magnesium) delayed-release capsules, for oral use (NDA 021153), is approved in 20 and 40 mg strengths and as Nexium (esomeprazole magnesium) for delayed-release oral suspension in 2.5 mg, 5 mg, 20, mg, and 40 mg strengths (NDA 021957) and 10 mg strength (NDA 022101). Please refer to Attachment 1 for a copy of the pertinent page from the "Approved Drug Products

with Therapeutic Equivalence Evaluations" (Orange Book) which lists the approved RLD products referenced in this petition.

For the additional capsule strengths, our client proposes using the administration options listed in the label for Nexium delayed-release capsules be followed: (1) capsule can be swallowed whole, (2) capsule can be opened and mixed with applesauce, or (3) capsule can be opened and the intact granules emptied into a syringe and delivered through the nasogastric tube. The NEXIUM (esomeprazole magnesium) for delayed-release oral suspension labeling only allows for dosing pediatric patients up to 11 years old by adding the unit dose packet powder to water.

Our client is proposing to provide capsule strengths across the entire dose range in the dosage and administration section of the approved package insert which provides pediatric patients up to 11 years old with two additional administration options (in applesauce and as a capsule) to the NEXIUM (esomeprazole magnesium) for delayed-release oral suspension option (in water). Additional administration options assists caregivers with adherence to complying with administration of the prescribed medication. In addition, there are no generic options at these additional dose strengths, so there may also be a cost benefit to patients.

The FDA-approved labeling for the RLD, NEXIUM, is provided in Attachment 2. The draft labeling for the proposed product is provided in Attachment 3.

For the reason mentioned above, the Commissioner should approve this petition no later than 90 days after this petition is submitted and authorize the submission of an ANDA for esomeprazole delayed-release capsules, 2.5mg, 5 mg, and 10 mg strengths.

C. Environmental Impact

The actions requested herein are subject to categorical exclusion under 21 CFR §25.31(a).

D. Economic Impact

An economic impact statement will be submitted upon request should the Commissioner determine such assessment is necessary in evaluating this petition.

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 that are unfavorable to the petition.

Please direct any questions or comments regarding this submission to my attention via phone at (202) 672-5430, e-mail at drosen@foley.com or facsimile at (202) 672-5399.

Respectfully submitted,

David L. Rosen, BS Pharm, JD

Attachments