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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 pantoprazole sodium for delayed-release oral suspension.

A. Action Requested

The Petitioner seeks a determination from the Commissioner of Food and Drugs that an ANDA may be submitted for pantoprazole sodium for delayed-release oral suspension containing 20 mg and 40 mg pantoprazole as enteric granules packaged in a unit dose capsule supplied in a bottle of 30 capsules instead of in a unit dose packet supplied in a unit dose carton of 30 packets.

B. Statement of Grounds

Our client would like to file an ANDA for pantoprazole sodium delayed- release for oral suspension, containing 20 mg and 40 mg pantoprazole as enteric granules, in a unit dose capsule supplied in a bottle of 30 capsules. The RLD product, PROTONIX (pantoprazole sodium) for Delayed Release Oral Suspension (NDA 022020), is approved as enteric granules containing 40

mg pantoprazole in a unit dose packet supplied in a unit dose carton of 30 packets. 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 product referenced in this petition.

Our client believes that a change in the granules primary packaging from a unit dose packet to a unit dose capsule does not pose questions of safety or effectiveness because the use, dose, and route of administration of the proposed drug product are the same as that of the listed drug product. The Instructions for Use labeling for the proposed product would clearly instruct patients to "open the capsule" instead of "open the packet". The remaining administration instructions would remain the same.

The proposed change in the primary packaging is a benefit to pediatric patients. Currently, the RLD is only available in packets containing 40 mg of pantoprazole. The RLD labeling recommends dosing of 20 mg for children $\geq$ 15 kg to < 40 kg. The labeling also states, "Do not divide the 40 mg PROTONIX For Delayed-Release Oral Suspension packet to create a 20 mg dosage for pediatric patients who are unable to take the tablet formulation." The proposed capsule product would allow pediatric patients to take the oral suspension product as a 20 mg dose.

In addition, the RLD is available in a delayed-release tablet form containing 20 mg or 40 mg of pantoprazole; should a patient disregard the label instructions and swallow the 20 mg or 40 mg capsule whole, there is not a safety concern because the same therapeutic benefit would be received whether taking the tablet or capsule. While the capsule size may be slightly larger than the tablets, a standard capsule size will be used for the proposed product so it will not be larger than other capsule products currently marketed. Both the tablets and granules are enteric coated to dissolve in the intestine, regardless of the vehicle used when administering the product.

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

For all the reasons mentioned above, the Petitioner respectfully requests that the Commissioner approve this petition no later than 90 days after this petition is submitted and authorize the submission of an ANDA for pantoprazole sodium delayed-release for oral suspension packaged in a capsule form.

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

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