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March 13, 2006

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

SUITABILITY PETITION

This petition is submitted pursuant to 21 CFR 10.20 and 10.30, as provided for in 21 CFR 314.93 and Section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act, to request the Commissioner of the Food and Drug Administration (FDA) to declare that the drug product Omeprazole delayed-release Tablets for oral administration in a 20 mg strength is suitable for submission as an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Omeprazole Tablets, 20 mg (proposed formulation), is suitable for submission as an ANDA. The Reference Listed Drug product (RLD) upon which this petition is based is Prilosec® OTC (Omeprazole magnesium delayed-release tablets equivalent to 20 mg Omeprazole) approved under a New Drug Application (NDA) 021-229.

This petition is submitted for a change in the salt form of the active ingredient in a listed drug containing the same active moiety. The Reference Listed Drug contains Omeprazole magnesium as the active ingredient and the proposed ANDA contains Omeprazole as the active ingredient. Both the drug products contain the same active moiety, Omeprazole. The drug, the route of administration, and the recommendations for use are the same as those of the listed drug product. The proposed product would differ only in active ingredient from the marketed product, Prilosec® OTC.

The proposed drug product is expected to demonstrate bioequivalence to the listed product; data will be submitted at a later date.

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B. Statement of Grounds

Section 505 (b) (2) of the Federal Food, Drug, and Cosmetic Act provides for the submission of an application for a new drug that differs in the salt form of an active moiety from that of a listed drug provided the FDA has approved a petition that proposed the filing of such an application.

This petition requests a change in active ingredient for the proposed drug from that of the reference listed drug, Omeprazole magnesium to Omeprazole.

The active ingredient of the proposed formulation is of the same pharmacological or therapeutic class as those of the reference listed drug.

The proposed formulation is expected to have the same therapeutic effect as the reference listed drug when administered to patients for each condition of use in the reference listed drug's labeling for which the applicant seeks approval.

The proposed formulation contains Omeprazole as active ingredient. Omeprazole is an active ingredient in many approved drug products. The orange book details of Omeprazole formulations as on 03.08.2006:

Application Number	Dosage form	Strength	Applicant
019-810	Capsule, delayed release pellets; oral	10 mg, 20 mg, 40 mg	Astra Zeneca
075-785	Capsule, delayed release pellets; oral	10 mg, 20 mg	Impax labs
-	Capsule, delayed release pellets; oral	10 mg, 20 mg	Several other generics got approval
021-636	For Suspension; oral	20 mg/packet,	Santarus
021-706	For Suspension; oral	40 mg/packet,	Santarus

As the active ingredient, Omeprazole, is approved in many formulations, it will not raise any issues of safety or efficacy in the proposed formulation.

Additional particulars of the proposed formulation and reference listed drug formulation are furnished herein:

Proposed Formulation:

Omeprazole Tablets 20 mg

Each delayed release tablet contains:
Omeprazole 20 mg

In this formulation Omeprazole base is used as a starting material and to provide alkaline environment sodium hydroxide is used (sodium content per tablet – 1.4 mg) in the process. A patent was filed on the proposed formulation technology and it differs from the formulation technology as used by the Innovator. Approved formulation excipients are used in developing the formulation. The inactive ingredients used in the formulation development : colloidal silicon dioxide, cross carmellose sodium, disodium hydrogen phosphate, glycerol, hydroxy propyl methyl cellulose, magnesium stearate, methacrylic acid copolymer type c, microcrystalline cellulose, polyethylene glycol, sodium bicarbonate, sodium hydroxide, sodium lauryl sulfate, talc and triacetin. All the inactive ingredients used are approved by FDA and within the limits specified for oral application based on Inactive Ingredients Data Base as provided by FDA.

Reference Listed Drug Formulation:

Prilosec® OTC tablets; Each delayed release tablet contains:
Omeprazole magnesium equivalent to Omeprazole 20 mg.

Name of the applicant: Astra Zeneca

Application number: NDA 021-229

Marketing status: OTC formulation

Indication: Treats frequent heartburn (occurs 2 or more days a week). Not intended for immediate relief of heartburn; this drug maytake 1 to 4 days for full effect For treatment of Heart Burns

Reference Listed Drug product uses Multi Unit Particulate System (MUPS) technology and formulation technology is patent protected. Orange Book listed the following patents in the application data base: 4786505, 4786505*PED, 4853230, 4853230*PED, 5690960, 5753265, 5817338, 5900424, 6403616, 6428810.

Similarities:

- Both the formulations are enteric coated to protect the active from getting degraded in the stomach.
- Both the formulations are tablet dosage forms
- Both the formulations contain 20 mg of Omeprazole

Dissimilarities:

- Reference Listed Drug product uses Omeprazole Magnesium
- Proposed formulation uses Omeprazole
- Multiunit particulates are enteric coated and compressed in to a tablet dosage form in the case of RLD
- Proposed formulation provides enteric coating to the final tablet dosage form

Supportive Evidence:

Esomeprazole Sodium is the active ingredient in Nexium® IV injectable approved in the NDA 021-689. Hence, providing sodium hydroxide for maintaining alkaline environment in a tablet dosage form would not have any impact on the safety and efficacy of the formulation.

Based on proof of concept bio-studies results comparing to the innovator, the proposed formulation is expected to demonstrate bio-equivalence to the reference listed drug product.

According to the approved labeling for the reference listed drug product, Prilosec®OTC (Omeprazole magnesium delayed-release tablet, equivalent to 20 mg Omeprazole) is recommended for a 14 day course of treatment, 1 tablet a day for 14 days.

The proposed labeling for the abbreviated product will be consistent with the reference listed drug labeling.

Also, the approved labeling for Prilosec®OTC (Omeprazole magnesium delayed-release tablet, equivalent to 20 mg Omeprazole) includes dosing recommendations of 20 mg/day doses. The labeling for the proposed strength of 20 mg will therefore be within the range of therapy allowed for in the approved label.

In summary, the proposed change in salt of the active ingredient in Omeprazole delayed-release tablets from that of the reference listed drug (i.e. a change from Omeprazole magnesium to Omeprazole) will not raise issues of safety or efficacy of the proposed product.

The proposed product will differ from the listed drug only in the salt form of the active ingredient. The indications, route of administration, intended patient population, and recommendations for use will remain the same as for the Prilosec® OTC product.

Therefore, there will be no difference in the safety and efficacy of the proposed Omeprazole delayed-release tablets than that of the Reference Listed Drug.

The label and package insert of the marketed product, Prilosec® OTC, is provided in Attachments 1 & 2 of this petition. The draft label and package insert for the proposed Omeprazole delayed-release 20 mg Tablets is provided in Attachments 3 & 4.

C. Pediatric Use Information

The Pediatric Research Equity Act, 2003, requires that applications submitted under section 505 of the Act, be evaluated for safety and efficacy in pediatric populations when the application is submitted for the following: A new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration.

The proposed petition seeks a change in salt form of active ingredient from that of the reference listed product, and therefore under the provisions of the Pediatric Research Equity Act, it is not necessary to evaluate the safety or efficacy in pediatric populations or seek a waiver or deferral for pediatric studies.

Further support that this petition for a change in salt form of active ingredient is that the proposed drug product is indicated for adults18 years of age and older.

D. Environmental Impact

The action of submitting and reviewing of this Suitability Petition will not normally be expected to have an environmental impact. Therefore, under 21 CFR 25.30(h), we request a categorical exclusion from the requirement to prepare an environmental assessment (EA), since, to the best of our knowledge, no extraordinary circumstances exist as indicated by 21 CFR 25.21.

E. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the agency.

F. Certification

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

Sincerely,

R Namburi

Ranga Namburi, Ph.D.
Vice President - Technical