TENSHI
KAIZEN PRIVATE LIMITED

August 3rd 2020

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane (HFA-305)
Rockville, MD 20852

Tenshi Kaizen Private Limited, submits this petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act ("FD&C Act") and 21 C.F.R. § 314.93, and in accordance with 21 C.F.R. § 10.20 and 21 C.F.R. § 10.30, to request that the U.S. Food and Drug Administration ("FDA") determine that the over-the-counter (OTC) drug product, Famotidine Orally Disintegrating Tablets (ODT), 20 mg is suitable for submission in an abbreviated new drug application (ANDA).

A. ACTION REQUESTED

The Petitioner requests that FDA determine that Famotidine Orally Disintegrating Tablets (ODT), 20 mg (OTC), is suitable for submission as an ANDA. The Reference Listed Drug (RLD) upon which this petition is based is Pepcid AC® (Product Number: 002), which FDA approved on September 23, 2003 under NDA 020325 and is marketed as an oral tablet in a 20 mg dosage strength. Tenshi seeks only a change in dosage form from that of the RLD, from immediate release tablets to orally disintegrating tablets (ODT).

B. STATEMENT OF GROUNDS

FD&C Act § 505(j)(2)(A)(iii) permits the submission of an ANDA for a drug product that differs in dosage form from the RLD after FDA has approved a petition submitted pursuant to FD&C Act § 505(j)(2)(C). Pepcid AC®, the RLD for the proposed OTC drug product is used for prevention and relief of heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages. A copy of the current Orange Book entry for Pepcid AC® is included as ***Attachment 1*** and a copy of the most recent available labeling for Pepcid AC® (April 9, 2019) is included as ***Attachment 2***.

Petitioner's proposed drug product in a different dosage form does not pose questions of safety or effectiveness because the indications, route of administration, intended patient population, and recommendations for use of the proposed drug product are the same as that of the RLD. As stated in the Drug Facts labeling for Maximum Strength Pepcid AC®:

To relieve symptoms for adults and children 12 years and over, the recommended dose of Maximum Strength Pepcid AC® is a 20 mg tablet taken with a glass of water. Do not chew. To prevent symptoms for adults and children 12 years or over, the recommended dose is a 20 mg tablet taken with a glass of water at any time from 10 to 60 minutes before eating food or drinking breverages that cause heartburn. Do not take more than 2 tablets in 24 hours.

The proposed orally disintegrating tablets would be a viable alternative to both of the currently marketed dosage forms[1], the oral tablet and the chewable oral tablet, and would provide ease of administration for those patients that have difficulty swallowing conventional tablets, or may have dysphagia. The product could also be taken without water, which may provide patients greater ease or convenience over traditional oral tablets.

Labeling of the proposed drug product will be the same as that of the RLD with differences only related to the dosage form. A side-by-side comparison of the RLD labeling and the proposed product draft labeling is included as ***Attachement 3***. The uses and warnings will remain the same as that of the RLD.

Based on FDA's Suitability Petition Database, FDA has approved the following petition for a change in dosage form for Famotidine products:

Docket No. 00P-1422: Petition filed by Yamanouchi Pharma Technologies, Inc. on July 19, 2000, approved on April 17, 2001, requesting permission to submit an ANDA for Famotidine Orally Disintegrating Tablets, 10 mg against Pepcid AC® (famotidine) Tablets, 10 mg, manufactured by Merck Research Laboratories. FDA's response and approval of the associated sutability petition is provided as ***Attachement 4***.

For the foregoing reasons, Petitioner requests that FDA finds that the proposed dosage form Famotidine Orally Disintegrating Tablets, 20 mg (OTC), is suitable for submission as an ANDA.

Additionally, Petitioner requests a waiver of the Pediatric Research Equity Act ("PREA"). PREA was enacted in December 2003 and amended the FD&C Act by requiring certain applications for a drug submitted under section 505 to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is deferred or waived. See FDC Act § 505 B(a)(1)(A). PREA applies to all applications for a new active ingredient, dosage form, indication, route of administration, or dosing regimen. However, PREA provides for a waiver from its requirements if the drug "does not present a meaningful therapeutic benefit over existing therapies for pediatric patients" and "Is not likely to be used in a substantial number of pediatric patients" FDC Act § 5058(a)(5)(A).

Because the product is not indicated in children less than 12 years of age, the petitioner requests a full waiver from the conduct of pediatric studies. The proposed drug product does not present a "meaninful therapeutic benefit" over the existing RLD in patients over 12 years old or other products with the same active ingredient, as it is the same active ingredient used in a similar manner. Furthermore, based on the nature of the

[1] Please be advised that NDA 020752, Pepcid RPD® (famotidine) Orally Disintegrating Tablets, 20 mg and 40 mg was approved on April 28, 1995 and is no longer commercially available.

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.

Additionally, FDA has waived the pediatric study requirements within the Suitability Petition filed by Yamanouchi Pharma Technologies, Inc. on July 19, 2000, and approved on April 17, 2001 (**Docket No. 00P-1422).** The Agency has determined that the proposed change in dosage form was subject to the Pediatric Rule, but had concluded that investigations are not necessary to demonstrate the safety and effectiveness of the proposed product in the pediatric population because the specific drug product was not intended to be marketed to children under the age of 12. Accordingly, the Agency waived the pediatric study requirement for the proposed drug product Famotidine Orally Disintegrating Tablets, 10 mg (OTC) as part of the approval of Suitability Petition 00P-1422. As such, Petitioner respectfully requests a PREA waiver.

C. ENVIRONMENTAL IMPACT

The petitioner claims a categorical exclusion under 21 CFR § 25.31.

D. ECONOMIC IMPACT

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. Petitioner hereby commits to promptly provide this information, if so requested.

E. CERTIFICATION

The undersigned certifies 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 is unfavorable to the petition.

Sincerely,
Tenshi Kaizen Private Limited

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Sangeetha. K
Head – Regulatory Affairs