TENSHI
KAIZEN PRIVATE LIMITED

October 19, 2023

ELECTRONIC SUBMISSION

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane (Room 1061)
Rockville, MD 20857

WITHDRAWAL CITIZEN PETITION - DOCKET NUMBER: FDA-2020-P-1728

Dear Sir/Madam,

Tenshi Kaizen Private Limited wish to inform the agency that we had submitted a Citizen Petition (docket no. FDA-2020-P-1728, dated August 03, 2020) electronically under Section 505(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 10.20, 10.30 and 314.93, requesting the agency to **determine** if the over-the-counter (OTC) drug product, Famotidine Orally Disintegrating Tablets (ODT), 20 mg [NDA 020325- Pepcid AC® (Product Number: 002)] is suitable for submission in an abbreviated new drug application (ANDA) and in addition seeking only a change in dosage form from that of the RLD, from immediate release tablets to orally disintegrating tablets (ODT).

Tenshi hereby wishes to withdraw the petition (docket no. FDA-2020-P-1728) dated August 03, 2020.

If you have any questions regarding this application or if you require any further details, please do not hesitate to contact me Sangeetha. K, Phone: +91 8068470947 (sangeetha.k@tenshi.co.in).

Sincerely,
Tenshi Kaizen Private Limited

Sangeetha k
Digitally signed by Sangeetha k
Date: 2023.10.19 15:42:16 +05'30'

Sangeetha. K
Global Head – Regulatory Affairs
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