



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

August 3, 2020

Sangeetha Karthik
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Bangalore, Karnataka, 560078 INDIA

Sent via email to: sangeetha.k@tenshi.co.in

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA determine that Famotidine Orally Disintegrating Tablets (ODT), 20 mg (OTC), is suitable for submission as an ANDA was received by this office on 08/03/2020.

It was assigned docket number FDA-2020-P-1728. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)