



Yamanouchi Pharma
Technologies, Inc.

Stanford Research Park
1050 Arastradero Road
Palo Alto, CA 94304
T: 650.849.8505 F: 650.849.8565

August 10, 2000

To: Dockets Management Branch
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: CITIZEN'S PETITION -- Suitability Petition for an Over-The-Counter (OTC) drug product, Famotidine Orally Disintegrating Tablets, 10 mg, docket numbers 00P-1422/CP 1 and 00P-1433/CP 1

Dear Sir or Madam:

Enclosed please find copies of two letters received by the Food and Drug Administration regarding docket numbers 00P-1422/CP 1 and 00P-1433/CP 1. Please note that 2 docket numbers were assigned for the same petition, Famotidine orally disintegrating tablets, 10 mg. We request the Agency to adjust its records and to permit the filing of docket number 00P-1422/CP 1 filed on 07/19/00.

Please contact me regarding any questions or comments at Phone: 1-877-342-0895 (toll free) or (650) 849-8587, or by Fax: (650) 849-7887 or (650) 849-8622, or by E-mail: rkrishna@ypharma.com.

Sincerely,

A handwritten signature in cursive script that reads "Raan V. Krishna".

Raan V. Krishna, Ph. D.
Manager, Regulatory Affairs

00P-1422



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

RECEIVED

JUL 28 2000

July 20, 2000

Raan V. Krishna, Ph.D.
Yamanouchi Pharma Technologies Inc.
Stanford Research Park
1050 Arastradero Road
Palo Alto, CA 94304

Dear Mr. Krishna:

Your petition requesting the Food and Drug Administration to permit the filing of an Abbreviated New Drug Application for an Over-The-Counter (OTC) drug product, Famotidine Orally Disintegrating Tablets 10mg, was received by this office on 07/19/00. It was assigned docket number 00P-1422/CP 1 and it was filed on 07/19/00. 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 in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, reading "Jennie C. Butler", is written in black ink.

Jennie C. Butler
Dockets Management Branch



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 3, 2000

Raan V. Krishna, Ph.D.
Yamanouchi Pharma Technologies, Inc.
Stanford Research Park
1050 Arastradero Road
Palo Alto, CA 94304

Dear Dr. Krishna:

Your petition requesting the Food and Drug Administration to approve an ANDA for OTC drug product Famotidine orally disintegrating tablets, 10 mg., a tablet that disintegrates quickly in the oral cavity, was received by his office on 08/03/00. It was assigned docket number 00P-1433/CP1 and it was filed on 08/03/00. 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 in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script that reads "Helen K. Harris".

Helen K. Harris
Dockets Management Branch

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dirección

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**PRIORITY
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From: Raan Krishna
Yamanouchi Pharma Technologies
1050 Arastradero Road
Palo Alto, CA 94304

To: Dockets Management Branch
US Food and Drug Administration
Dept. of Health + Human Services
Room 1-23
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Rockville, MD 20857

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