MAIVA PHARMA PVT LTD
Formerly Global Pharmatech

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Email: info@maivapharma.com | Web: www.maivapharma.com
CIN: U24231KA1993PTC013976

October 12, 2022

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services (HFA 305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam:

Maiva Pharma Private Limited (Maiva) is submitting this citizen petition pursuant to Code of Federal Regulations sections 21 CFR 10.20, 21 CFR 10.30 and 21 CFR 314.161 requesting the Commissioner of Food and Drug Administration (FDA) to provide a determination whether a listed drug has been voluntarily withdrawn for the reasons other than safety or efficacy.

A. Action Requested

Maiva requests that the Commissioner of the Food and Drug Administration ("FDA") determine whether the drug product, Miacalcin® (calcitonin salmon, USP) Injection, 100 USP Units/ mL approved under NDA 017808 held by Mylan Ireland Limited, was voluntarily withdrawn for the reasons other than safety or efficacy.

B. Statement of Grounds

The Food and Drug Administration (FDA) maintains a list of drug products which are eligible for submission as Abbreviated New Drug Applications (ANDAs). The list, Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the "Orange Book", lists all FDA approved drug products.

Registered Office
No:688, Ground Floor, 6th Main, III Block,
BEL Layout, Vidyaranyapura, Bangalore-560097

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The RLD, Miacalcin® (NDA # N017808) was originally approved in two strengths:

1. Miacalcin® (calcitonin salmon, USP) Injection, 100 USP Units/ mL approved on July 3, 1986. This presentation appears to be intended for single dose administration.

2. Miacalcin® (calcitonin salmon, USP) Injection, 400 USP Units/ 2 mL (200 USP Unit/ mL) approved on March 29, 1991. This presentation is labeled as a multi-dose vials.

Currently, only the Miacalcin® (calcitonin salmon, USP) Injection, 400 USP Units/ 2 mL (200 USP Unit/ mL) multi-dose vial presentation is available in the US market. The Miacalcin® (calcitonin salmon, USP) Injection, 100 USP Units/ mL has been discontinued from the supply and now appear in the "Discontinued Section" of the Orange Book (See annexure 1 – Orange Book details).

Under FDA regulations, drugs are withdrawn from the market if the Agency withdraws or suspends approval of the drug application for the reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 C.F.R. § 314.162). Applicants may also voluntarily withdraw safe and effective drug products from sale for business or other reasons. The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for the reasons of safety or efficacy before an ANDA that refers to that listed drug may be approved (21 CFR 314.161 (a)(1)).

Hence, Maiva requests that the FDA determine whether the RLD, Miacalcin® (calcitonin salmon, USP) Injection, 100 USP Units/ mL listed as "discontinued" in the Orange Book was withdrawn for the reasons other than safety or efficacy.

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If FDA determines that the RLD, Miacalcin® (calcitonin salmon, USP) Injection, 100 USP Units/ mL was not discontinued for reasons related to safety or efficacy, then this will allow for approval of an ANDA referencing this discontinued drug product if such approval is requested.

C. Environmental Impact

In accordance the requirements set forth in 21 CFR 25.31, the petitioner hereby requests a categorical exclusion from the requirements to prepare an environmental impact assessment.

D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification

Maiva certifies that to the best of our knowledge, this petition includes all information and views on which the petition relies and that includes the representative data and the information known to the petitioner, which are unfavourable to the petition.

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The contact information for our designated U.S. Agent is located below. If you have any questions or need additional information, please contact the undersigned.

Ms. Anne Toland

Sr. Consultant

Meridan Consulting, LLC

Phone Number: 1-215-792-6888

E-mail: Atoland@meridanconsulting.com

Sincerely,

Manikyarao Tirumani

Digitally signed by Manikyarao Tirumani
Date: 2022.10.12 22:47:11 +05'30'

Manikyarao Tirumani
Assistant Vice President & Head Regulatory Affairs
Maiva Pharma Private Limited
No: 32, SIPCOT Industrial Complex,
Phase I, Hosur – 635 125, Tamil Nadu, India
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Annexure 1: Orange Book details of listed drug, Miacalcin® 400 USP Units/2 mL and 100 USP Units/ mL, NDA 017808 held by Mylan Ireland Limited.

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May 11, 2022

Office of Generic Drugs (HFD-600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North VII
7620 Standish Place
Rockville, MD 20855

Re: U.S. Agent Appointment Letter
Appointment of Meridan Consulting, LLC as U.S. Agent for:
Maiva Pharma Private Limited

This letter will serve to advise the Food and Drug Administration that Meridan Consulting, LLC acting through its authorized representative, Anne Toland, has been appointed as the U.S. Agent to act on behalf of Maiva Pharma Private Limited with respect to communication and correspondence with the FDA. The contact information for the authorized representative at Meridan Consulting, LLC is as follows:

Company name	:	*Meridan Consulting, LLC*
DUNS number	:	*831142208*
Contact person's name	:	*Ms. Anne Toland*
Title	:	*Sr. Consultant*
Telephone number	:	*1-215-792-6888*
Address	:	*300 Carnegie Center Drive Suite 150* *Princeton, New Jersey 08540*
Fax number	:	*1-215-638-8841*
E-mail address	:	*Anne@ATLregulatory.com*

Our U.S. Agent is appointed and designated by our company to submit and receive correspondence on scientific or administrative matters pertaining to our facility and FDA submissions. Any planned inspection by the FDA of our facility may be arranged through our U.S. Agent. If you have any questions, please do not hesitate to contact the undersigned by email, fax or by telephone.

Sincerely,

Bhaskar Krishna Arumugam, PhD, MBA
Managing Director and CEO
Maiva Pharma Private Limited
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cc: Meridan Consulting, LLC