



October 13, 2022

Manikyarao Tirumani
Maiva Pharma Private Limited
No: 32, SIPCOT Industrial Complex,
Phase I, Hosur – 635 125, Tamil Nadu, INDIA

Sent via email to: manikya.t@maivapharma.com

Dear Petitioner:

Your submission requesting that the Commissioner 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salmon, USP) Injection, 100 USP Units/ mL approved under NDA 017808 held by Mylan Ireland Limited, was voluntarily withdrawn for the reasons other than safety or efficacy was received and processed under CFR 10.30 by this office on 10/12/2022.

It was assigned docket number FDA-2022-P-2517. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)

cc: Anne Toland (AToland@meridanconsulting.com)