

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

February 17, 2023

Re: Docket No. FDA-2022-P-2517

Dear Manikyarao Tirumani:

This letter responds to your citizen petition received on October 12, 2022, requesting that the Food and Drug Administration (FDA) determine whether a listed drug has been voluntarily withdrawn for the reasons other than safety or efficacy.

FDA has reviewed its records and determined that Miacalcin (calcitonin salmon) injection, 100 USP Units/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Miacalcin (calcitonin salmon) injection, 100 USP Units/mL, in the “Discontinued Drug Product List” section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-3600.

Sincerely,

**Donna C.
Tran -S**

Donna Tran
Office of Regulatory Policy
Center for Drug Evaluation and Research

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Enclosure