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

Re: Docket No. 2005P-0360/CP

Dear Sir/Madam:

Please refer to Novartis Pharmaceuticals Corporation's approved NDA No. 20-313 for Miacalcin® (calcitonin salmon) Nasal Spray, which has been cited by third parties in the course of the above-referenced administrative proceeding (FDA Docket No. 2005P-0360/CP1, filed 09/06/2005).

Novartis is submitting this correspondence because public Docket No. 2005P-0360/CP1 represents the second Citizen Petition filed with the Agency involving Novartis' Miacalcin Nasal Spray product (the first having been filed in FDA Docket No. 2004P-0015/CP1). As with the first such petition, the manner in which the above-referenced Citizen Petition has been written suggests that it was filed on behalf of Novartis. It was not. We want to clarify for the Agency that Novartis was not aware of either the first or second petitions until they were filed, and had no involvement in their development or submission. Currently, Novartis does not have and does not intend to take a position on the above-referenced Citizen Petition. Likewise, we did not take a position on the first petition. Furthermore, Novartis does not know on whose behalf Foley Lardner submitted this petition.

If the Agency has any questions or requires any additional information in connection with this submission, please contact me by telephone at (862) 778-3798.

Respectfully Submitted,

A handwritten signature in cursive script that reads 'Roxanne Tavakkol'.

Roxanne Tavakkol  
Associate Director  
Drug Regulatory Affairs  
Novartis Pharmaceuticals Corporation

cc: Jane Axelrad, J.D., Director, Office of Regulatory Policy (HFD-005)  
Mr. Gary J. Buehler, Director, Office of Generic Drugs (HFD-600)  
Elizabeth H. Dickinson, Esq., Office of the Chief Counsel (GCF-001)