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Food and Drug Administration  
Rockville, MD 20857

August 10, 2004

Mr. Anthony C. Celeste  
AAC Consulting Group  
7361 Calhoun Place  
Suite 500  
Rockville, Maryland 20855-2765

Dear Mr. Celeste:

Your petition requesting the Food and Drug Administration to determine that 10 ml/125 mg of elemental iron injection drug product is suitable for an ANDA based on the listed drug Ferrlecit Injection 5 ml/62.5 mg of elemental iron, was received by this office on 8/09/2004. It was assigned docket number 2004P-0360/CP 1 and it was filed on 08/10/2004. 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,

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management