



July 9, 2007

FILE COPY

Mark E. DuVal
DuVal & Associates, PA
3902 IDS Center
80 South 8th Street
Minneapolis, MN 55402

Dear Mr. DuVal:

Your petition, on behalf of Ferrosan A/S, Sydmarken 5, DK-2860 Soeborg, requesting the Food and Drug Administration to refrain from finalizing and promulgating a final regulation for the Proposed Reclassification and the final Draft Special Controls guidance unless and until an updated and complete administrative record is made available to the public; reopen the rulemaking for the Proposed Reclassification to allow submission of comments based on the administrative record; convene another, appropriately compromised, Advisory Panel to review FDA's Proposed Reclassification regulation and Draft Special Controls; and stay further administrative action on the Proposed Reclassification and Draft Special Controls was received by this office on 07/06/2007. It was assigned docket number 2006N-0362/CP1 and it was filed on 07/09/2007. 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

2006N-0362

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