



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

September 8, 2004

FILE COPY

Cristina Neves
Hikma Farmaceutica (Portugal), Lda
Estrada Do Rio Da Mo, n 8, 8A – 8B
Fervenca
2705-906 Terrugem SNT Portugal

Dear Ms Neves:

Your petition requesting the Food and Drug Administration to determine that betamethasone sodium phosphate plus betamethasone acetate has been voluntarily shortened from distribution and sale for safety or efficacy reasons, was received by this office on 09/07/2004. It was assigned docket number 2004P-0406 and it was filed on 09/07/2004. 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,

Gloria Ortega
Deputy Director
Division of Dockets Management
Office of Management Programs
Office of Management

2004P-0406

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