



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FILE COPY

June 30, 2000

Terrance C. Coyne, M.D.
Medeva Pharmaceuticals, Inc
P.O. BOX 1710
755 Jefferson Road
Rochester, New York 14603

Dear Mr. Coyne:

Your petition requesting the Food and Drug Administration not approve of any abbreviated new drug applications (ANDAs) for generic versions of Zaroxolyn Tablets (metolazone tablets, USP) or Mykrox Tablets, was received by this office on 06/27/00. It was assigned docket number OOP-1370/CP1 and it was filed on 06/27/00. 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,

Jennie C. Butler
Dockets Management Branch

OOP.1370

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