



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

September 14, 2004

FILE COPY

Mr. Anthony Bruno
Warner Chilcott
100 Enterprise Drive
Rockaway, New Jersey 07866

Dear Mr. Bruno:

Your petition requesting the Food and Drug Administration to require that an ANDA applicant for doxycycline hyclate capsule products containing powder or similar fill and relying on DORYX as the reference listed drug first obtain FDA's acceptance of a suitability petition for a change in dosage form, was received by this office on 09/13/2004. It was assigned docket number 2004P-0417/CP 1 and it was filed on 09/14/2004. 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

2004P-0417

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