



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Anthony Bruno
Executive Vice President
General Counsel
Warner Chilcott
100 Enterprise Drive
Rockaway, New Jersey 07866

Re: Docket No. 2004P-0417/CP1

Dear Mr. Bruno:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated September 10, 2004. Your petition requests, among other things, that FDA: (1) confirm that capsules containing coated doxycycline hyclate pellets in a delayed release formulation are not the same dosage form as capsules containing doxycycline hyclate powder or fill other than pellets; and (2) require that an applicant for an abbreviated new drug application 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.

FDA has yet to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0417

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