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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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FEB 27 2006

Minnie Baylor-Henry
Vice-President, Medical and Regulatory Affairs
Ortho-McNeil Pharmaceutical, Inc.
Camp Hill Road
Ft. Washington, PA 19034

RE: Docket No. 2005P-0352

Dear Ms. Baylor-Henry:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on August 31, 2005. Your petition requests that the Agency require that standard bioequivalence criteria be applied separately to oxybutynin and its active metabolite, desethyloxybutynin, to ensure that approved generic versions of Ditropan XL are both bioequivalent and clinically equivalent to the innovator product.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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

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

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