



APR 23 2002

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Marcy Macdonald
Associate Director, Regulatory Affairs
Apotex Corp.
50 Lakeview Parkway
Suite 127
Vernon Hills, Illinois 60061

Docket No. 01P-0495/CP1

Dear Ms. Macdonald:

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 October 24, 2001. You ask the Agency to determine that the non-titrated dosing regimen originally approved for Ultram tablets was not withdrawn from the labeling for reasons of safety or effectiveness, that a generic Ultram labeled with the discontinued dosing regimen will not be less safe or effective than Ultram with its current labeling, and that TorPharm's¹ abbreviated new drug application (ANDA) for a generic Ultram may use the discontinued dosing regimen.

FDA has been unable 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 possible given the numerous demands on the Agency's resources.

Sincerely yours,

Janet W. Woodcock, M.D.
Director
Center for Drug Evaluation and Research

¹ Apotex Corp. is the U.S. agent for its corporate affiliate TorPharm.

01P-0495

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