DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

November 6, 2003

FILE COPY

Jonathan P. Dohnalek
Manager, Regulatory Affairs
Hospital Products Division
Abbott Laboratories
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

Dear Mr. Dohnalek:

Your petition requesting the Food and Drug Administration to permit abbreviated new drug applications to be filed for Ondansetron Hydrochloride Injection (4 mg/2mL and 8 mg/4 mL prefilled syringes) and Ondansetron Hydrochloride Injection Premixed (8, 12, 16, 20 and 24 mg in 50 mL 5% Dextrose Injection) was received by this office on 11/06/2003. It was assigned docket number 2003P-0519 and it was filed on 11/06/2003. 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

2003P-0519

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