



MAR 22 2006

Food and Drug Administration
Rockville MD 20857

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William W. Vodra, Esq.
Arnold & Porter LLP
555 Twelfth Street, NW
Washington, DC 20004-1202

Re: Docket No. 2005P-0402/CP 1

Dear Mr. Vodra:

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 September 28, 2005, and submitted on behalf of Ross J. Baldessarini, M.D. and Frederick K. Goodwin, M.D. Your petition requests that the Agency take two actions. First, you request that FDA determine, on the basis of a comprehensive review of published studies, that lithium is safe and effective for reducing the incidence of suicide and suicide attempts in patients with manic-depressive illness. Second, you request that the Agency order or permit the labeling of approved lithium carbonate and lithium citrate drugs to include an amended indication and related prescribing information on a class-wide basis. You ask that the labeling for these products be amended to add: "Lithium carbonate or citrate is indicated to reduce the incidence of suicide and suicide attempts in patients with manic-depressive illness (bipolar I disorder)."

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,

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

2005P-0402

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