



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 25 2006

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Charles J. Raubicheck, Esq.
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, New York 10151

Re: Docket No. 2005P-0436/CP1

Dear Mr. Raubicheck:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on behalf of Banner Pharmacaps Inc. and received on October 28, 2005. Your petition requests that FDA refuse to approve the section 505(b)(2) new drug application (NDA) 21-863, submitted by Ranbaxy Laboratories Ltd. (Ranbaxy), seeking approval for Ibuprofen Liquid Filled Gelatin Capsules, 200 mg, on the ground that the Ranbaxy NDA, as amended, does not contain the appropriate patent certification. In addition, you filed an amendment and three supplements to the petition, revising your request.

FDA has been unable to reach a decision on your petition because it raises significant 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
Associate Director for Policy
Center for Drug Evaluation and Research

2005P-0436

LET 2