



FEB -3 2000

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Alan H. Kaplan
Richard S. Morey
Peter R. Mathers
Kleinfeld, Kaplan and Becker
1140 Nineteenth Street, N.W.
Washington, D.C. 20036-6601

Re: Docket No. 99P-1589/CP1 & PSA1

Dear Messrs. Kaplan, Morey, and Mathers,

This letter responds to the citizen petition and petition for stay of action dated May 18, 1999, on behalf of Purdue Pharma L.P. concerning NDA 20-932, held by Roxane Laboratories (Roxane). This response also addresses your supplemental filings dated July 19, 1999, August 20, 1999, October 6, 1999, and November 12, 1999. For the reasons discussed below, your petitions are granted in part and denied in part.

In your May 18, 1999, citizen petition, you request that NDA 20-932 covering Roxicodone (oxycodone HCl) Sustained-Release Tablets, 10 mg and 30 mg, submitted and held by Roxane (together with any pending supplements or amendments to the application for other dosage strengths of extended-release oxycodone HCl tablets), be recognized as an application covered by 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the Act). You also request that the October 26, 1998 effective approval of that application be declared by the Food and Drug Administration (FDA) to be null and void as having been issued in violation of FDA's statutory authority and Purdue's rights under the 1984 Amendments to the Act. You further request that any future approval of a Roxane new drug application for a sustained release oxycodone tablet be issued by FDA only after Roxane complies with all statutory and regulatory standards for 505(b) applications, including, if a 505(b)(2) application, appropriate certifications to patents covering Purdue's OxyContin Controlled Release Tablets.

In your May 18, 1999, petition for stay of action, you request that the Commissioner stay the effective date of the approval and any pending approvals until the Commissioner has fully evaluated and ruled on your associated citizen petition.

FDA has carefully considered the arguments in your petitions, the information in your supplemental filings, and all other relevant and available information. On February 3, 2000, with Roxane's concurrence, FDA stayed the approval of NDA 20-932. The stay will remain in effect until such time as (1) Roxane submits additional data, (2) FDA has reviewed those data, and (3) FDA has determined that the submitted data support a finding of safety and effectiveness without reliance on investigations to which Roxane has no right of reference. Roxane has never marketed Roxicodone Sustained-Release Tablets under NDA 20-932 and this stay prohibits marketing under NDA 20-932 while the stay is pending. Consequently, your request that the

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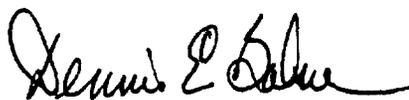
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approval be declared null and void is granted to the extent that FDA will not permit Roxane to market under NDA 20-932 until the stay is lifted, and will not lift the stay until Roxane has demonstrated safety and effectiveness without reliance on investigations to which Roxane has no right of reference.

Your request that FDA treat the approved application as an application submitted under 505(b)(2) is denied, as FDA does not consider this application to have been submitted under 505(b)(2). FDA grants your request regarding any future approval of NDA 20-932 and will not lift the stay until it determines that Roxane has complied with all of the statutory and regulatory standards for the type of approval that Roxane seeks. Your petition for a stay pending the Commissioner's review of the citizen petition is denied as moot.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dennis E. Baker". The signature is fluid and cursive, with a long horizontal stroke at the end.

Dennis Baker
Associate Commissioner for
Regulatory Affairs