



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Commissioner

HFA-365

Office of Policy and Planning  
Food and Drug Administration  
5600 Fishers Lane, HFW-11  
Rockville, MD 20857-3333

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March 23, 2004

Richard S. Morey  
Peter R. Mathers  
Jennifer A. Davidson  
Kleinfeld, Kaplan and Becker, LLP  
1140 Nineteenth Street, NW  
Washington, DC 20036-6606

Re: Docket No. 04P-0006/PSA1

Dear Mr. Morey, Mr. Mathers, and Ms. Davidson:

This responds to your petition for stay of action (Petition) dated January 6, 2004, submitted pursuant to 21 CFR § 10.35 on behalf of Purdue Pharma L.P. (Purdue), requesting that the Food and Drug Administration (FDA or the Agency) stay final approval and/or the effective date of final approval of any and all abbreviated new drug applications (ANDAs) for oxycodone hydrochloride controlled-release products that list OxyContin (oxycodone HCl controlled-release) Tablets as the reference listed drug unless and until the products covered by those ANDAs are the subject of appropriate risk management programs (RMPs) consistent with the RMP for OxyContin. Specifically, you request that FDA stay final approval of any ANDA that lists OxyContin as the reference listed drug until (1) the Commissioner has evaluated Purdue's three supplements to incorporate the company's RMP into the approved labeling for OxyContin; (2) ANDA applicants adopt labeling that conforms to that for OxyContin; and (3) ANDA applicants have developed and fully implemented RMPs, supported by appropriate staff and resources, that are consistent with that for OxyContin. For the reasons stated below, your petition for stay of action is now moot.

**I. BACKGROUND**

On December 19, 2003, Purdue submitted a Changes Being Effected supplement advising FDA of changes to the "Warnings" section of the package insert for OxyContin that Purdue was implementing immediately. A second supplement submitted on January 6, 2004, sought to include a new subsection within the "Precautions" section of the package insert for OxyContin entitled "Prescriber Information Resources." This new subsection would incorporate educational elements of the RMP into the OxyContin package insert. On January 13, 2004, Purdue submitted a third supplement seeking to include the RMP for OxyContin in the approved labeling for the product. Copies of these submissions are included in the docket for this petition.

**II. DISCUSSION**

You request that FDA stay final approval of any ANDA that lists OxyContin as the reference listed drug until (1) FDA has evaluated Purdue's three supplements for changes to the approved

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labeling for OxyContin; (2) ANDA applicants adopt labeling that conforms to that for OxyContin; and (3) ANDA applicants have developed and implemented RMPs that are consistent with that for OxyContin (Petition at 2). For the reasons stated below, your request is now moot.

**A. FDA Has Evaluated the OxyContin Labeling Supplements**

You request that FDA not approve any ANDAs for generic versions of OxyContin before evaluating Purdue's three labeling supplements to incorporate aspects of the OxyContin RMP into OxyContin labeling. FDA has reviewed the supplements, and on March 23, 2004, the Agency issued letters to Purdue stating that each of the three supplements was not approvable under section 505 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355) and 21 CFR § 314.125(b). Therefore, your petition for stay is moot with regard to this issue.

**B. The Labeling for Approved Generic Versions of OxyContin Conforms to the Labeling for OxyContin**

You request that FDA not approve any ANDAs for generic versions of OxyContin until the ANDA applicants adopt labeling that conforms to the OxyContin labeling (Petition at 2). You maintain that the OxyContin RMP should be included in the approved labeling for OxyContin in accordance with your labeling supplements, and you maintain that generic versions of OxyContin must include the same elements of an RMP in the labeling for their products (Petition at 7-10).

On March 23, 2004, FDA approved ANDAs for oxycodone hydrochloride controlled-release tablets submitted by Endo Pharmaceuticals Inc. (Endo) and Teva Pharmaceuticals USA (Teva). In accordance with section 505(j)(4)(G) of the Act, approved ANDAs must have the same labeling as the labeling for OxyContin. As stated above, FDA's March 23, 2004, letters to Purdue found that the proposed labeling supplements were not approvable. Accordingly, the labeling for a generic version of OxyContin is not required to include the language regarding an RMP that Purdue proposed in its supplements.

In light of the foregoing, your petition for stay is moot with regard to this issue.

**C. The Manufacturers of Approved Generic Versions of OxyContin Will Implement RMPs That Are Consistent With the OxyContin RMP**

You request that FDA stay approval of ANDAs for a generic version of OxyContin until the applicants have implemented RMPs consistent with OxyContin (Petition at 2). This request is moot because Endo and Teva have created and agreed to implement, prior to marketing, RMPs whose elements are consistent with those of the OxyContin RMP. These RMPs, which were developed in consultation with the appropriate personnel at FDA, all include the following key elements:

- Clear, strong wording in the labeling for professionals and patients

- Comprehensive professional education programs on the appropriate use of opioids in the treatment of pain
- Surveillance for misuse, abuse, addiction, diversion, and overdose and other related serious adverse events
- Specific interventions to be undertaken when monitoring reveals misuse, abuse, addiction, diversion, or overdose or other related serious adverse events.

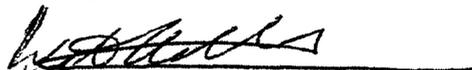
We note that approval of an RMP of the scope and nature described in your January 13, 2004, supplement, like that developed by the ANDA applicants, is not necessary prior to implementation; indeed, Purdue has stated that it has already implemented its RMP.

In light of the fact that the generic products will have RMPs consistent with that for OxyContin, your petition for stay is moot with regard to this issue.

### III. CONCLUSION

For the reasons stated above, your petition for stay of the approval of ANDAs for oxycodone hydrochloride controlled-release products that list OxyContin Tablets as the reference listed drug is moot.

Sincerely,



William K. Hubbard  
Associate Commissioner  
for Policy and Planning