



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFD-305  
Public Health Service

AUG 15 2005

Food and Drug Administration  
Rockville MD 20857

Barbara A. Van Rooyan  
Kirk W. Van Rooyan, M.D.  
105 Englehart Drive  
Folsom, CA 95630

3153 5 AUG 17 A9:44

Re: Docket No. 2005P-0076/CP1 and  
SUP1 and 2

Dear Dr. and Mrs. Van Rooyan:

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 February 17, 2005. Your petition requests that the Agency temporarily withdraw the approval of Oxycontin and Palladone until they are chemically reformulated by their sponsor, Purdue Pharma (Purdue) to incorporate anti-abuse features, and that FDA narrow the indications for both drugs.

I would like to call your attention to the fact that we recently requested that Purdue suspend sales and marketing of Palladone because of the potential for severe side effects if it is taken with alcohol. On July 13, 2005, we announced that Purdue had agreed to FDA's request. Information about this action is publicly available on FDA's Internet website at: <http://www.fda.gov/cder/drug/infopage/palladone/default.htm>.

FDA has been unable to reach a decision on your petition because it raises complex 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-0076

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