



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 10 2006

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Food and Drug Administration  
Rockville MD 20857

Ms. Rosei Rocha-Judd  
2217 2<sup>nd</sup> Avenue N  
Number 304  
Birmingham, AL 35203

Re: Docket No. 2005P-0463

Dear Ms. Rocha-Judd:

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 November 15, 2005. Your petition requests that the Commissioner of Food and Drugs recommend scheduling of tramadol under the Controlled Substances Act in light of the patient safety and public health considerations discussed in your petition.

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-0463

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