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Richard M. Cooper
Michael K. Stern
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, D.C. 20005-5901

Re: Docket No. 2005P-0267/CP1

Dear Messrs. Cooper and Stern:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition filed on June 28, 2005, on behalf of the American College of Gastroenterology. Your petition requests that the Agency remove from the labeling of propofol (Diprivan) the warning that the drug product should be administered only by persons trained in the administration of general anesthesia and not involved in the surgical/diagnostic procedure.

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-0267

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