



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

June 28, 2005

FILE COPY

Mr. Richard M. Cooper
Williams and Connolly LLP
725 Twelfth Street, N.W.
Washington, D.C. 20005

Dear Mr. Cooper:

Your petition on behalf of American College of Gastroenterology requesting the Food and Drug Administration to remove from the labeling for propofol (Diprivan) the warning that propofol should be administered only by persons trained in the administration of general anesthesia, rather than by other qualified medical professionals, was received by this office on 06/28/2005. It was assigned docket number 2005P-0267/CP 1 and it was filed on 06/28/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0267

ACK 1