



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 1 2006

Sidney M. Wolfe, M.D.
Peter Lurie, M.D., M.P.H.
Mr. Nicholas Stine
Public Citizen
Frederic Solomon, M.D.
c/o Public Citizen
1600 20th Street, N.W.
Washington, D.C. 20009

Re: Docket No. 2005P-0115/CP1

Dear Drs. Wolfe, Lurie, and Solomon, and Mr. Stine:

This letter responds to your citizen petition dated March 24, 2005, asking the Food and Drug Administration (FDA) to immediately remove from the market pemoline (Cylert, manufactured by Abbott Laboratories, and all generic versions). You state that pemoline should not be marketed because the drug is known to have caused at least 21 cases of liver failure and has no unique therapeutic benefit over other drugs for the treatment of attention deficit hyperactivity disorder (ADHD).

Abbott informed FDA on March 24, 2005, that it intended to discontinue marketing Cylert. Abbott ceased commercial distribution of Cylert on September 16, 2005. The generic firms that marketed pemoline under abbreviated new drug applications have also ceased marketing the drug. Because all pemoline products have been removed from the market, the outcome sought by your petition has been achieved and thus, as a practical matter, your petition is moot. Furthermore, to the extent your petition seeks withdrawal of any drug's approval under section 505(e) of the Federal Food, Drug, and Cosmetic Act, FDA does not find such additional action necessary at this time because the drugs are no longer being marketed. Thus, FDA denies any such request in your petition.

FDA has not asked the manufacturers of pemoline to recall those products that may remain in the distribution chain. On October 24, 2005, you wrote a letter to FDA's Acting Commissioner Andrew von Eschenbach urging the Agency to immediately tell the manufacturers of pemoline to recall all outstanding supplies of the drug. FDA has advised healthcare professionals who prescribe pemoline of the need to transition patients to an alternative therapy (<http://www.fda.gov/cder/drug/InfoSheets/HCP/pemolineHCP.htm>), and the product is no longer being marketed. Accordingly, we do not think such a recall is necessary.

Sincerely,


Steven K. Galson, M.D., M.P.H.
Director
Center for Drug Evaluation and Research

2005P-0115

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