# Pemoline removed from US market

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Pemoline, an older therapy for attention-deficit/hyperactivity disorder (ADHD), was sold by Abbott Laboratories under the brand name Cylert until May 2005, when the company discontinued the product. According to FDA's announcement, manufacturers of generic versions of the drug have now agreed to stop marketing their formulations of pemoline in this country.

FDA, through its MedWatch drug safety reporting system, stated that pemoline products will remain available until existing stocks held by wholesalers and pharmacies are exhausted. Clinicians who prescribed pemoline for patients with ADHD must select an alternate agent, the agency stated.

FDA stated that it had received 13 reports of liver failure that resulted in liver transplant or death among patients receiving pemoline despite the existence of strong warnings in the product's labeling. Although the use of pemoline declined drastically after the addition to the labeling in 1999 of a black box warning about the risk of liver failure, 1 case of liver failure occurred after the label was revised, according to the agency.

Overall, FDA stated, the reporting rate for liver failure among pemoline users is 10 to 25 times higher than would be expected in the general population.