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October 25, 2005

FDA Alert – Healthcare Professionals

The FDA has issued an Alert for Healthcare Professionals regarding Pemoline tablets and chewable tablets, marketed as Cylert®.

The FDA has concluded that the overall risk of liver toxicity from Cylert and generic pemoline products outweighs the benefits of the drug. Cylert® is a central nervous system stimulant indicated in the treatment of ADHS. This product is considered a second line therapy for ADHD because of its association with life threatening hepatic. In May 2005 Abbott Laboratories chose to stop sales and marketing of this product and all generic companies have agreed to stop sales and marketing also.

More information regarding the withdrawal of this drug can be found at:

<http://www.fda.gov/cder/drug/InfoSheets/HCP/pemolineHCP.htm>

Cylert®, or any of its generics, will remain available through pharmacies and wholesalers until supplies are exhausted; no additional product will be available.

4D Pharmacy Management has completed a query of the claims system to identify beneficiaries receiving pemoline. The query select began included dates of service from July 1, 2005 to present. A list of those beneficiaries will be forwarded to our clients under separate cover. If you do not receive a password-protected e-mail within 24 hours of this notice you may assume that your plan had no beneficiaries meeting the query criteria.

Alert for Healthcare Professionals Pemoline Tablets and Chewable Tablets (marketed as CYLERT)

FDA ALERT [10/2005]: Liver Injury Risk and Market Withdrawal

The Agency has concluded that the overall risk of liver toxicity from Cylert and generic pemoline products outweighs the benefits of this drug. In May 2005, Abbott chose to stop sales and marketing of Cylert in the U.S. All generic companies have also agreed to stop sales and marketing of this product (Pemoline tablets and chewable tablets). Cylert is a central nervous system stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). This product is considered second line therapy for ADHD because of its association with life threatening hepatic failure (see **BOXED WARNING in product label and patient package insert, available**

http://www.fda.gov/cder/foi/label/2003/016832s022_017703s018lbl.pdf

FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program at

1-800-FDA-1088 or <http://www.fda.gov/medwatch/report/hcp.htm>

Recommendations

Health Care Professionals who prescribe Cylert, or any of its generics, should transition their patients to an alternative therapy. Cylert will remain available through pharmacies and wholesalers until supplies are exhausted; no additional product will be available.

Data Summary

FDA is aware of 13 reports of liver failure resulting in liver transplant or death, usually within four weeks of onset of signs and symptoms of liver failure. Although the absolute number of reported cases of liver failure with pemoline is not large, the reporting rate for liver failure with pemoline is 10 to 25 times greater than the background rate of liver failure in the general population.

Despite diminished use of Cylert and generic pemoline products since the addition of the boxed warning in 1999 (about 1/5 the number of prescriptions now compared to before the boxed warning) and restrictive labeling (e.g., boxed warning, second line therapy, Medguide), a risk of liver failure remains (FDA is aware of 1 new case of pemoline-associated liver failure since the introduction of the boxed warning in 1999). Given the availability of multiple other drug treatments for ADHD, including 1 that is not scheduled and several products that can be given

once a day, FDA has concluded that the risk of liver failure with this drug outweighs the potential benefits.