GBS
Group Benefit Services

Compliance Alert

December 6, 2010

FDA recommends the withdraw of the pain medication propoxyphene

This letter is to inform you of new, important information regarding the pain medication propoxyphene. On November 19, 2010, the U.S. Food and Drug Administration (FDA) recommended that all manufacturers of propoxyphene withdraw their products from the U.S. market. Propoxyphene is sold under a variety of names as a single-ingredient or in combination with acetaminophen. The FDA reviewed new data that shows the drug can cause serious toxicity to the heart, even when used at therapeutic doses. This data, combined with other available information, have led the FDA to conclude that the safety risks of propoxyphene outweigh its benefit for pain relief.

The FDA recommends that healthcare professionals stop prescribing and dispensing propoxyphene-containing products. In addition, they should contact patients currently taking these products and ask them to discontinue the drug, inform them of the risks associated with propoxyphene and discuss alternative pain management strategies. Patients are advised to dispose of unused propoxyphene in household trash by following the recommendations outlined in the Federal Drug Disposal Guidelines.

Additional information regarding this market withdrawal can be found on FDA's website at: www.fda.gov/Drugs/DrugSafety/ucm234338.htm.

This communication is not intended to be legal advice and should not be construed as legal advice. If you have any legal questions or concerns about your plan, GBS recommends seeking counsel from an ERISA attorney.

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