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BAYER VOLUNTARILY WITHDRAWS BAYCOL

FDA today announced that Bayer Pharmaceutical Division is voluntarily withdrawing Baycol (cerivastatin) from the U.S. market because of reports of sometimes fatal rhabdomyolysis, a severe muscle adverse reaction from this cholesterol-lowering (lipid-lowering) product. The FDA agrees with and supports this decision.

Baycol (cerivastatin), which was initially approved in the U.S. in 1997, is a member of a class of cholesterol lowering drugs that are commonly referred to as "statins." Statins lower cholesterol levels by blocking a specific enzyme in the body that is involved in the synthesis of cholesterol. While all statins have been associated with very rare reports of rhabdomyolysis, cases of fatal rhabdomyolysis in association with the use of Baycol have been reported significantly more frequently than for other approved statins.

Fatal rhabdomyolysis reports with Baycol have been reported most frequently when used at higher doses, when used in elderly patients, and particularly, when used in combination with gemfibrozil (LOPID and generics), another lipid lowering drug. FDA has received reports of 31 U.S. deaths due to severe rhabdomyolysis associated with use of Baycol, 12 of which involved concomitant gemfibrozil use.

Rhabdomyolysis is a condition that results in muscle cell breakdown and release of the contents of muscle cells into the bloodstream. Symptoms of rhabdomyolysis include muscle pain, weakness, tenderness, malaise, fever, dark urine, nausea, and vomiting. The pain may involve specific groups of muscles or may be generalized throughout the body.

Most frequently the involved muscle groups are the calves and lower back; however, some patients report no symptoms of muscle injury. In rare cases the muscle injury is so severe that patients develop renal failure and other organ failure, which can be fatal.

Bayer Pharmaceutical Division has announced plans to withdraw Baycol to the pharmacy level. Pharmacies will be instructed to return the product to the manufacturer for a refund.

Patients who are taking Baycol should consult with their physicians about switching to alternate medications to control their cholesterol levels. Patients taking Baycol who are experiencing muscle pain or are also taking gemfibrozil should discontinue Baycol immediately and consult their physician.

There are five other statins available in the U.S. that may be considered as alternatives to Baycol. They are: lovastatin (Mevacor), pravastatin (Pravachol), simvastatin (Zocor), fluvastatin (Lescol), and atorvastatin (Lipitor).

For further information regarding the withdrawal of Baycol, patients and physicians can contact Bayer Customer Service 1-800-758-9794 or the FDA's Drug Information Office at 301-827-4573 or 1-888-INFO-FDA, or go to "Baycol Information" on FDA's Website.

US Food & Drug Administration

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This is the retyped text of a letter from Bayer Corporation. Contact the company for a copy of any referenced enclosures.

August 8, 2001

RE: Market withdrawal of **Baycol**[®] (cerivastatin)

Dear Healthcare Professional:

I am writing to inform you of very important new safety information about Baycol (cerivastatin) and rhabdomyolysis.

Rhabdomyolysis is a serious, potentially fatal, adverse effect of all statin drugs, including Baycol. It can occur with statin monotherapy, though the risk appears to be increased significantly by concomitant use of gemfibrozil (Lopid).

Our ongoing scrutiny of post marketing reports of rhabdomyolysis, including fatalities, has revealed an increased reporting rate of rhabdomyolysis with Baycol relative to other statins, especially when gemfibrozil is co-prescribed. These data also suggest an increased reporting rate of rhabdomyolysis at the 0.8 mg dose of Baycol alone.

Bayer Corporation has already placed a contraindication in the Baycol product prescribing information sheet against co-prescription with gemfibrozil and issued letters to healthcare professionals warning against co-prescription of these two drugs. Despite these and other actions, Bayer has continued to receive reports of rhabdomyolysis when gemfibrozil is prescribed as a co-medication. Since the co-prescription of Baycol and gemfibrozil has continued despite communications by Bayer against this practice, the company has decided to take the following voluntary action to prevent further cases of rhabdomyolysis:

Effective immediately, Bayer has discontinued the marketing and distribution of all dosage strengths of Baycol. Patients who are currently taking Baycol should have their Baycol discontinued and be switched to an alternative therapy.

Bayer is taking this action as part of an ongoing commitment to patients and their healthcare providers to ensure patient safety.

It is important to you forward any adverse event information associated with the use of Baycol to Bayer Corporation at 1-800-288-8371. You can also report the information directly to the FDA via the MedWatch system at 1-800-FDA-1088, by mail (using a postage paid form), or the Internet at www.fda.gov/medwatch.

If you have further questions regarding this action on Baycol, please contact Bayer customer service at 1-800-758-9794.

Yours sincerely,
E. Paul Mac Carthy, MD
Vice President,
Head U.S. Medical Science