May 14, 2002

Dear Healthcare Professional,

We would like to call to your attention a situation involving counterfeit labeling of Combivir® (lamivudine plus zidovudine) Tablets. GlaxoSmithKline has received four reports of bottles labeled as Combivir Tablets that actually contained another GSK medicine, Ziagen® (abacavir sulfate) Tablets. The company has determined that counterfeit labels for Combivir were placed on two bottles of Ziagen and labels on another two bottles are suspect. Both medicines are used as part of combination regimens to treat HIV infection.

These incidents appear to be isolated and limited in scope. No injuries or adverse reactions have been reported. Company tests have shown no problems with the medicine itself. GlaxoSmithKline is working with the U.S. Food and Drug Administration to investigate.

Involved in the counterfeit labeling cases were 60-count bottles of Combivir Tablets, which contain 150-milligrams of lamivudine and 300 milligrams of zidovudine, and 60-count bottles of 300-milligram tablets of Ziagen.

Should any patients for whom you have prescribed Combivir contact you with questions or concerns about their current prescription, you may find useful the following information, which we are providing to healthcare professionals and pharmacies across the country and which we are providing to the media:

Pharmacists, physicians, and patients should immediately examine the contents of each Combivir bottle to confirm it does not contain Ziagen tablets. The two kinds of tablets are easily distinguishable. Combivir is a white capsule-shaped tablet engraved with "GX FC3" on one side; the other side of the tablet is plain. Ziagen is a yellow capsule-shaped tablet engraved with "GX 623" on one face; the other side is plain The Combivir label shows a color photo of the tablet.

If a pharmacy discovers a bottle of Combivir® that contains Ziagen, we have asked the pharmacist to notify **GSK** at **888-825-5249** (toll free). If you have any patients who have questions about the medicine in their Combivir bottle, please direct them to return it to their pharmacist. They may also call GSK at 888-825-5249. Full product information is available on the GlaxoSmithKline website, **www.gsk.com**.

The risk to patients is primarily due to the fact that approximately 5% of individuals who receive abacavir sulfate in Ziagen® or Trizivir® (abacavir sulfate, lamivudine and zidovudine) Tablets have developed a potentially life-threatening hypersensitivity reaction. Symptoms generally resolve after discontinuing the medication, however, patients who have had a hypersensitivity reaction to Ziagen® are advised to never take the medication again. Patients taking Combivir® would not have been advised about the hypersensitivity reaction and how to take Ziagen® safely because Combivir® does not contain abacavir sulfate. Patients who have had a hypersensitivity reaction to abacavir yet take Ziagen® or Trizivir® again experience more severe symptoms within hours that may include life-threatening hypotension (lowering of the blood pressure) and death. In addition, the replacement of Combivir® which contains two antiviral drugs with Ziagen®, a single antiviral, may decrease the effectiveness of a patient's treatment regimen.

At GlaxoSmithKline, patient safety is our first priority. We appreciate your help as we try to resolve this matter as quickly as possible. GSK is taking all possible steps to protect the quality and integrity of our products. If you have any additional questions, please contact us at 1-888-825-5249.