March 29, 2007

Dear Pharmacy Professional,

We would like to call to your attention an apparent third-party tampering that caused misbranding of Ziagen® (abacavir sulfate) Tablets as Combivir® (lamivudine and zidovudine) Tablets and employed counterfeit labels for Combivir Tablets. Both Combivir and Ziagen are medicines used as part of combination regimens to treat HIV infection.

These incidents appear to be isolated and limited in scope to one pharmacy in California; to date, there have been no reports of similar incidents in other cities or in other states. No injuries or adverse reactions have been reported. Company tests have shown no problems with the medicine itself; both Ziagen and Combivir are authentic drug product. GlaxoSmithKline is working with the U.S. Food and Drug Administration to investigate.

Involved in the misbranding cases were two 60-count bottles of Combivir Tablets. Combivir Tablets (in a legitimate bottle) contain 150 milligrams of lamivudine and 300 milligrams of zidovudine; however, the misbranded bottles of Combivir contained 300 milligram tablets of Ziagen. The counterfeit labels identified Lot No. 6ZP9760 with expiration dates of April 2010 and April 2009.

If you have bottles of Combivir Tablets in your pharmacy, you should immediately examine the contents of each bottle of Combivir to confirm that it does indeed contain tablets of Combivir. You may choose to counsel patients who have recently received Combivir. The Combivir and Ziagen 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. Please see the enclosed photos of Combivir and Ziagen.

If you discover a bottle of Combivir that contains anything but Combivir tablets, please notify the GSK Response Center at 1-888-825-5249 (toll free) between 8:00 a.m. and 8:00 p.m. ET, Monday through Friday.

The risk to patients is primarily due to the fact that approximately 8% of individuals who receive abacavir sulfate in Ziagen Tablets, Trizivir (abacavir sulfate, lamivudine and zidovudine) Tablets or Epzicom™ (abacavir sulfate and lamivudine) 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 abacavir-containing products are advised to never take the medication again. Patients taking Combivir would not have been advised about the hypersensitivity reaction and how to take abacavir-containing products safely because Combivir does not contain abacavir sulfate (abacavir). Patients, who have had a hypersensitivity reaction to abacavir and take Ziagen, Trizivir or Epzicom again, experience more severe symptoms within hours that may include life-threatening hypotension 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 or your patients have any additional questions, please contact the GSK Response Center at **1-888-825-5249 between 8:00 a.m. and 8:00 p.m. ET, Monday through Friday**. Full product information is available on the GlaxoSmithKline website, www.gsk.com.

For additional helpful information on how to avoid unsafe medicines and vendors, see the following website sponsored by The Partnership for Safe Medicines: http://www.safemedicines.org/resources/documents/safesourcing.pdf

Combivir bottle

Ziagen box

Combivir Tablet – engraved side

Ziagen Tablet – engraved side

Combivir Tablet – back side

Ziagen Tablet – back side