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## New Information From FDA On Alleged Problems With Ketek Safety Study 3014

Thursday, November 01, 2007

**October 2007 FDA Letter Says Aventis Did Not Follow Regulations And Statutory Requirements; Company Contends Study Conducted In Good Faith**

(Posted by Tom Lamb at [DrugInjuryWatch.com](http://DrugInjuryWatch.com))

On October 24, 2007 the FDA posted on its web site a copy of an 11-page "Warning Letter" to Sanofi-Aventis (SNY) about problems with Ketek Study 3014.

In her October 25, 2007 *Wall Street Journal* article, "FDA Says Aventis Failed To Act on Ketek Drug Fears", Anna Wilde Mathews provided this summary the FDA's Ketek letter:

In yesterday's letter, the FDA said visits from an Aventis contractor and the drug maker's own audits documented "serious protocol violations and regulatory noncompliance by multiple clinical investigators." The agency said it was "unable to find evidence" that the company either fixed the problems or threw the problematic doctors out of the study and told the FDA. The FDA also faulted Aventis for failing to make sure the study was properly conducted and for allowing unqualified investigators to participate in the trial.

According to an October 25, 2007 story, "[Sanofi slammed by FDA over failure to act on Ketek fraud](#)", by Kristy Barnes that was posted on [DrugResearcher.com](http://DrugResearcher.com):

[Study 3014 of Ketek (telithromycin) was] carried out between 2001 and 2002 after the FDA said that it needed more safety information on Ketek following fears that it could cause liver problems. The studies were carried out by Pharmaceutical Products Development (PPD) on behalf of Aventis, prior to its merger with Sanofi-Synthelabo.

In July 2002, Aventis submitted the results of study 3014 to the FDA. Subsequent data validation inspections by the agency of several clinical investigators participating in the study raised red flags and the FDA requested in January 2003 that Aventis provide information on its sponsor monitoring and auditing of clinical investigator sites for the trial.

Aventis subsequently provided this information to the FDA and following a lengthy investigation, the agency has now concluded that: "Aventis did not adhere to the applicable statutory requirements and FDA regulations governing the conduct of clinical investigations".

At least two Sanofi-Aventis representatives have disputed the FDA's suggestion that Aventis acted improperly as regards its Study 3014 concerning the safety of Ketek.

As reported by Kim Dixon in "U.S. FDA cites Sanofi for shoddy study oversight", published online by *Reuters* October 24, 2007:

Sanofi-Aventis spokeswoman Emmy Tsui said the company intends to provide a detailed response to the letter.

She said the study was conducted in good faith, but has been the subject of much discussion. Sanofi has acknowledged that "various deviations occurred, including investigator fraud, and FDA did not rely upon this study in approving Ketek," she added.

And returning to [the October 2007 Ketek story by Kristy Barnes](#) on DrugResearcher.com:

Salah Mayhaoui, head of product communications for Sanofi-Aventis told DrugResearcher.com that: "Study 3014 was the first large "real world" study of an antibiotic and Aventis conducted this study in good faith."

"However, non-conformance in the form of deviations [from protocol] and other issues occurred, including clinical investigator fraud."

Mayhaoui said that the firm would provide a "detailed response" to the FDA's letter in the coming days. As part of this response we will "highlight some of the steps Aventis took to prevent the problems that occurred in 3014."

He said that at this point he did not know the next course of action that the FDA may take in regard to this matter. "I think they will review our arguments and then it is up to them to decide what happens next."

We will watch for further developments regarding this controversial clinical study of Ketek and, more generally, for new reports of liver damage and liver failure associated with the use of this particular antibiotic.

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