# FDA Conducts A Self-Critical Analysis Of Its Early Communications (ECs) Program

## There Was Apparently A Brief Discussion About Effect Of ECs At July 2009 Agency's Drug Safety Oversight Board Meeting

(Posted by Tom Lamb at www.DrugInjuryWatch.com on August 27, 2009, see http://bit.ly/4tB5Rr)

The Public Summary for the July 16, 2009 meeting of the FDA's Drug Safety Oversight Board includes the main points of what appears to be a self-critical analysis of the agency's relatively new Early Communications about Ongoing Safety Reviews (ECs) program. In relevant part:

> **Follow-up actions to the 21 Early Communications released since 2007**
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> The Executive Director of the DSB presented a follow-up on 21 ECs issued from August 2007 to July 2009. Elements of an EC were given along with a brief description of each EC, the projected date for follow-up, actual date of follow-up, and the follow-up actions. The following lessons were learned:
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> - The media's and public's reaction has been generally positive.
> - FDA could improve upon their estimated timeframe for follow-up as it has been imprecise with a few of the issued ECs.
> - Companies can be significantly affected by an EC despite FDA's disclaimer (that states FDA has not reached a conclusion but is studying the potential safety issue) that accompanies the communication.
> - The words in our disclaimer are not easily understood and interpreted by some of the public.

The most recent ECs from the FDA is "Early Communication about an Ongoing Safety Review Orlistat (marketed as Alli and Xenical)", which was issued on August 24, 2004.

Our coverage of this FDA action on August 24 ran with the sub-headline "FDA Early Communication Makes Clear That No Definite Association Between Liver Injury And Orlistat Has Been Established At This Time".

The response from GlaxoSmithKline about this FDA notice about a safety review of Alli and Xenical, simply titled "GlaxoSmithKline Statement Confirming alli Safety", was issued on August 24, 2009.

We would be interested in hearing your opinion about the FDA's Early Communications about Ongoing Safety Reviews (ECs) program.

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Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
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