FDA Transparency Task Force Will Hold Its Second Public Meeting On November 3, 2009

Emerging Safety Issues Concerning FDA-Regulated Products Is One Issue For Discussion Listed in October 2009 Federal Register Notice

(Posted by Tom Lamb at www.DrugInjuryWatch.com on October 6, 2009; see http://bit.ly/2SSVLU)

In the Federal Register for October 5, 2009 the FDA gave notice about a second public meeting to discuss issues related to transparency at the agency to be held in Washington, DC on November 3, 2009.

As you may recall, in the June 3, 2009 Federal Register the FDA first announced it would begin to set up a new Transparency Task Force within the agency whose purpose is to recommend ways by which there could be more timely disclosure about FDA regulatory and safety decisions. In that same notice the FDA informed us about the scheduling of a first public meeting intended to solicit recommendations on how the FDA can make more available, useful, and understandable information on its activities and decisions. That first Transparency Task Force public meeting was convened on June 24, 2009.

Returning to the October 5, 2009 Federal Register notice -- Food and Drug Administration Transparency Task Force; Public Meeting; Request for Comments -- in summary the FDA has requested comment on early communication about emerging safety issues concerning FDA-regulated products, disclosure of information and product applications that are abandoned or withdrawn by the applicant before approval, and communication of agency decisions about pending product applications. Comments are due by November 6, 2009.

In more detail, from the October 2009 FDA notice:

> The second public meeting will be conducted as a series of three moderated discussion groups covering these three topics. The specific topic for each discussion will be presented in the form of a case study. Only one discussion group will be held at a time. Following each moderated discussion, Task Force members may ask questions of the participants in each discussion group. Others in attendance at the public meeting then will have an opportunity to comment on the issues discussed during the public comment period that will occur after each discussion group. At least 7 days in advance of the meeting, the initial scenarios of the case studies for each of the three topics will be made available on the Internet. The initial scenarios will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at http://www.regulations.gov. The initial scenarios will also be available on FDA's Web site at http://www.fda.gov/transparency along with the agenda for this meeting. The complete case studies will be available in the same locations after the public meeting....

As for the three general issues for discussion listed in the October 2009 FDA notice in the Federal Register, the first one, titled "Emerging Safety Issues Concerning FDA-Regulated Products", is of the most interest to us.

We will continue to monitor developments concerning the relatively new FDA Transparency Task Force, including reports about this second public meeting and notices of any additional public meetings in the future.

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.
http://www.DrugInjuryWatch.com