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A legal update from Dechert's Intellectual Property and Life Sciences Groups

# The FDA's Move Towards Increased Transparency Could Threaten the Confidentiality of Submitted Data

On June 2, 2009, the Food and Drug Administration (FDA) announced the formation of a task force to develop recommendations for enhancing the transparency of the Agency's operations and decision-making process. On June 3, 2009, the FDA also announced that it will hold "a public meeting to solicit recommendations from interested persons on ways in which the FDA can make useful and understandable information about FDA activities and decisionmaking more readily available to the public."[1] These actions follow two January 21, 2009 memoranda by President Obama to the executive agencies directing them to work toward making key information readily available to the public and expressing commitment to transparency and openness of government.

Entities required to submit confidential, trade secret and/or private information to the FDA, such as pharmaceutical companies that submit confidential test data, should track and participate in this move towards transparency closely to ensure that the Agency takes into account and continues to ensure appropriate measures to protect such information going forward.

[1] http://edocket.access.gpo.gov/2009/E9-12902.htm

## The FDA's Historical Commitment to Preserving Confidential Information

A myriad of overlapping regulations dictate the FDA's handling of information and responding to public inquiry. These restrictions balance on the one hand the Agency's responsibility to safeguard information entrusted to the Agency with the principles of open government and transparency. Indeed, in a March 13, 2009 FDA-wide memorandum, the Commissioner reminded the Agency staff of the "imperative" to be "vigilant" in fulfilling the obligation to protect information submitted confidentially while following the principles of transparency outlined by President Obama on January 21, 2009. The Commissioner also reminded Agency staff that failure to follow disclosure procedures dictated by the various governing laws could result in the FDA being sued for damages, and that violations of such regulations could result in disciplinary action and/or individual criminal liability.

## The Mission of the Transparency Task Force

In establishing the Transparency Task Force, the FDA explained that the guiding mission will be to make useful and understandable information available to the public in a timely and user-friendly fashion. The Agency further explained that any recommendations should be consistent with the Agency's "goal of appropriately protecting confidential information."

In establishing the specific mandates for the Transparency Task Force, the Agency stated that it will:

- Seek public input on issues related to transparency;
- Recommend ways that the agency can better explain its operations compatible with the appropriate protection of confidential information;
- Identify information the FDA should provide about specific agency operations and activities, including enforcement actions and product approvals;
- Identify problems and barriers, both internal and external, to providing useful and understandable information about FDA activities and decision-making to the public;
- Identify appropriate tools and new technologies for informing the public;
- Recommend changes to the FDA's current operations, including internal policies and guidance, to improve the agency's ability to provide information to the public in a timely and effective manner;
- Recommend legislative or regulatory changes, if appropriate, to improve the FDA's ability to provide information to the public; and
- Submit a written report to the commissioner on the Transparency Task Force's findings and recommendations.

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm163899.htm

## The Public Hearing

The public meeting will be held June 24, 2009, from 8 a.m. to 5 p.m., at the National Transportation Safety Board (NTSB) Conference Center, 429 L'Enfant Plaza, SW., Washington, DC 20594. Although the meeting is open to the public, persons interested in attending the meeting must register by June 17, 2009.

## To Submit Comments

Parties wishing to submit comments may make a presentation at the public hearing. In addition, interested parties may submit written or electronic comments.

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## Practice group contacts

If you have questions regarding the information in this legal update, please contact the author or the Dechert attorney with whom you regularly work. Visit our Life Sciences page.

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