## [ Alerts and Updates ]

# FDA Seeks Comments on "Risk Information" in Advertising from Pharmaceutical and Medical Device Manufacturers

**May 28, 2009**

On May 26, 2009, the FDA issued and gave interested parties 90 days to comment on a draft guidance for industry titled "Presenting Risk Information in Prescription Drug and Medical Device Promotion." Drafted with the input of at least four FDA divisions, the FDA contends that the draft guidance does not set new standards for advertising. The draft guidance explains and provides examples of the reasoning the FDA follows when evaluating whether the risk and benefit presentations in a particular promotional piece create an accurate "net impression" of a product's risks and benefits.

The FDA's basic three-part rule in evaluating advertisements is that they:

- "cannot be false or misleading in any particular";
- "must reveal material facts about the product being promoted, including facts about the consequences that can result from the use of the product as suggested in the promotional piece"; and
- "should present information about effectiveness and information about risk in a balanced manner."

Claiming to rely on "a vast scientific body of knowledge regarding human cognition," the draft guidance proceeds to explain the various factors that can influence an FDA evaluation of a promotional piece.

While the FDA maintains that it will not require manufacturers to convey an identical number of risks and benefits, it will consider the numbers included when determining whether the communication, as a whole, provides an accurate and non-misleading impression of the product. The draft guidance cautions, however, that "simply satisfying one of the above factors (e.g., devoting the same amount of time or space to risk and benefit information) will not necessarily make a promotional piece accurate and non-misleading." The draft guidance also describes its relationship to the FDA Physician Labeling Rule for prescription drugs and also addresses issues related to a drug's package insert as well as formatting issues.

## For Further Information

If you have questions concerning this draft guidance or would like more information, please contact Frederick R. Ball, any of the other health law lawyers in the Pharmaceutical & Biotechnology industry group or the attorney in the firm with whom you are regularly in contact.