Alerts and Updates

FDA Requests Comments On Improving Regulatory Rules

May 3, 2011

On February 2, 2011, U.S. President Barack Obama issued a memorandum for the heads of agencies and departments concerning Executive Order 13563, "Improving Regulation and Regulatory Review." One of the provisions of the executive order was the affirmation of retrospective reviews by agencies of their existing significant regulations "that may be outmoded, ineffective, insufficient, or excessively burdensome."

On April 27, 2011, the U.S. Food and Drug Administration (FDA) published a request in the *Federal Register*, stating that it sought public comment on how FDA could revise its existing review framework to meet the obligations of Executive Order 13563.

- In particular, FDA is seeking public comment on which, if any, regulations should be reviewed at this time.
- FDA has indicated it is particularly interested in comments that identify regulations that are impediments to innovation and in suggestions on how those regulations could be improved.
- FDA has requested that commentators focus on rule changes that would achieve a broad public impact.
- Finally, FDA has requested that comments reference a specific regulation by the Code of Federal Regulations, and provide specific information on what needs to be changed and why.

A proposal should also include any available data on the cost or economic impact of the current rule and the proposed modification. FDA has emphasized that it is not accepting comments on proposed rules as part of this process. Comments are due with the agency no later than June 27, 2011.

For Further Information

If you have any questions about this *Alert*, please contact Frederick (Rick) R. Ball, any member of the Pharmaceutical, Pharmacy & Food industry group or the attorney in the firm with whom you are regularly in contact.