ALERTS AND UPDATES

FDA Issues "Non-Binding" Park Doctrine Criteria for Potential Referral of "Responsible Corporate Officials" for Prosecution for Alleged Violations of the Food, Drug, and Cosmetic Act

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The U.S. Food and Drug Administration ("FDA") recently set forth, in its *Regulatory Procedures Manual* for FDA personnel, criteria for when it would refer a matter for potential prosecution under the *Park* doctrine. In essence, the *Park* doctrine provides for criminal liability (first-time misdemeanor and possible subsequent felony) under the federal Food, Drug and Cosmetic Act ("FDCA") without proof that a corporate official acted with intent or even negligence.

Prosecution under the *Park* doctrine is possible even if the responsible corporate official lacked knowledge or did not participate in the specific offense. The FDA stated it would consider:

- The corporate official's knowledge of and actual participation in the violation;
- Whether the violation involves actual or potential harm to the public;
- Whether the violation is obvious;
- Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
- Whether the violation is widespread;
- Whether the violation is serious;
- The quality of the legal and factual support for the proposed prosecution; and
- Whether the proposed prosecution is a prudent use of FDA resources.

The FDA went on to state that it would be "futile to attempt to define or indicate by way of illustration either the categories of persons that may bear a responsible relationship to a violation or the types of conduct that may be viewed as causing or contributing to a violation of the Act."

Finally, the FDA stated that the factors are solely for guidance of FDA personnel and that the absence of any of the factors listed above does not mean that referral is inappropriate when other factors exist.

Analysis

Unfortunately, these criteria provide little additional guidance as to when the FDA will refer a matter for *Park* doctrine prosecution. That being said, responsible corporate officials at companies with a history of violations (evidenced by receiving Form FDA 483s and warning letters) or when the violations pose potential or actual harm to the public may be at particular risk for a *Park* doctrine referral. Corporate officials in companies in these circumstances may want to consistently consult with their legal counsel and take the steps necessary to address the concerns raised by the FDA.

In addition, prudent corporate officers will ensure that the company follows current Good Manufacturing Practices (GMPs) and maintains vibrant corporate compliance programs and standard operating procedures which, among other things, provide for:

- identification of potential violations of the FDCA;
- reporting to the appropriate responsible supervisory authority when such violations are found; and
- implementing corrective measures when needed.

Not doing so may put the responsible corporate official at increased risk for a *Park* doctrine referral.

For Further Information

If you have any questions about this *Alert*, please contact Frederick (Rick) R. Ball, any of the health law lawyers in the Pharmaceutical & Biotechnology industry group, any member of the White-Collar Criminal Law group or the attorney in the firm with whom you are regularly in contact.