FDA Publicly Releases Guidelines for *Park* Prosecutions Following FOIA Appeals

The Food and Drug Administration (FDA) advised Ropes & Gray today that it has published its criteria for *Park* doctrine prosecutions of responsible corporate officers in its Regulatory Procedures Manual. Under *United States v. Park*, a corporate official may be convicted of a misdemeanor violation of the Food Drug and Cosmetic Act (FDCA) without personally engaging in wrongdoing, or even knowing about another person's violation of the statute, provided the official had the responsibility or authority to prevent or correct the FDCA violation but failed to do so.

FDA announced its intent to push for increased use of criminal misdemeanor prosecutions of responsible corporate officials in a letter to Senator Charles Grassley (R-IA) released on March 4 of last year, but, until now, has declined to make available the criteria and procedures it had adopted to drive the selection of these prosecutions.

In the "non-binding" criteria that it has now released, FDA confirms that knowledge of and actual participation in the violation are not a prerequisite to prosecution, though they are relevant facts when deciding whether to recommend charging an individual, and that a misdemeanor conviction of an individual may serve as the basis for debarment by FDA. Notably absent from FDA's criteria is any consideration of efforts by the corporate official or the corporation to prevent and detect the type of misconduct that occurred.

FDA also indicated that it would consider:

- the individual's position in the company and relationship to the violation;
- whether the official had the authority to correct or prevent 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 agency resources.

FDA's "Special Procedures and Considerations for Park Doctrine Prosecutions" (section 6-5-3) is available here.

FDA's public disclosure of these *Park* considerations and procedures follows efforts by Ropes & Gray to secure release of this information under the Freedom of Information Act. On March 8, 2010, Ropes & Gray filed a request with FDA under FOIA seeking all documents containing FDA's criteria and procedures governing *Park* doctrine enforcement actions. In the absence of any response from FDA, Ropes & Gray submitted an administrative appeal on November 3, 2010. On November 23, 2010, FDA responded to that appeal by stating that its Office of Chief Counsel "has no responsive records." Ropes & Gray submitted a second administrative appeal on December 20, 2010, disputing that contention. Earlier today, a FOIA representative from FDA advised Ropes & Gray that the agency has publicly released the *Park* doctrine criteria and they are now available on FDA's website.

If you would like to discuss the foregoing or any other related matter, please contact any member of Ropes & Gray's FDA Practice or Government Enforcement Practice or your usual Ropes & Gray advisor.