decision to invoke the fraud policy with respect to an ANDA or 505(b)(2) NDA sponsor, or even a contract manufacturer with a significant role in preparation of an ANDA or 505(b)(2) NDA, could result in delays of one to a number of years in ANDA or 505(b)(2) NDA approval.

Substantial inspectional issues related to apparent cGMP problems may have the same practical effect as the "fraud policy." The FDA may decline to approve the firm's applications and supplements until all cGMP issues have been resolved and the firm has been "rehabilitated," often using the same process used when the "fraud policy" has been invoked.

Debarment

In response to irregularities in the generic drug industry, the FDC Act was amended in 1992 to include debarment provisions.* Both individuals and business entities can be debarred if convicted of certain crimes associated with a lack of trustworthiness (e.g., fraud, perjury, and obstruction of justice); a high managerial agent can also be debarred if he or she had knowledge of such activity and failed to take remedial action. All drug applications are required to include a certification that the sponsor did not use and will not use in any capacity the services of a debarred person in connection with the application. Thus, ANDA and 505(b)(2) NDA sponsors have an obligation to ensure that they do not employ debarred individuals and do not use, directly or indirectly, the services of an individual or business entity that has been debarred.†

CONCLUSION

In addition to the technical hurdles that a prospective generic drug sponsor must overcome, there are a number of obstacles that many would characterize as being of a legal nature. Uncertainties about how the FDA is implementing and interpreting some statutory provisions, such as 180-day generic drug exclusivity, along with the possibility of litigation, complicate business planning in many cases. A prospective ANDA or 505(b)(2) NDA sponsor facing a situation that could pose hurdles of this type would be well advised to seek appropriate regulatory and legal advice.

* 21 USC § 335a.

† FDA's debarment list is available at www.fda.gov/ora/compliance_ref/debar/default.htm. Accessed June 13, 2013. To date, over 100 individuals have been debarred, the great majority of them permanently.