rejected a challenge to FDA's decision that the ANDA product only had to be shown to be bioequivalent to the reference product being copied, not to predecessor versions of the reference product mentioned in the innovator product's labeling.* With this history of judicial deference to FDA's interpretation of bioequivalence, it seems relatively unlikely that a successful challenge to FDA decisions in this area will be mounted in the future.

An increasing number of innovator drugs that pose special risks are being approved with limited distribution systems under FDA's authority to impose Risk Evaluation and Mitigation Strategies (REMS),† discussed in Risk Evaluation and Mitigation Strategies below. Some innovator companies have used limited distribution procedures as a basis for refusing to sell product samples to would-be ANDA sponsors, thereby blocking generic competition. Legislation may be necessary to resolve this matter.

Prescription-to-OTC Switches

The innovator sponsor's decision to switch its drug product from prescription to over-the-counter (OTC) status could present additional obstacles to generic firms. If the supplemental NDA providing for OTC labeling is supported by essential clinical studies, the innovator firm is entitled to 3 years of exclusivity during which no ANDA could be approved. Moreover, under FDA policy, an ANDA or 505(b)(2) NDA could no longer be approved based on the previously approved prescription labeling.‡

Even if the innovator is not entitled to exclusivity, a prescription-to-OTC switch near the date of the innovator's patent expiration is likely to cause some delays in ANDA approvals, as generic firms would be required to create, and obtain FDA approval for, new labeling and packaging. If the innovator product were switched to OTC status after final ANDA approval, the FDA would presumably give the ANDA sponsor a reasonable length of time to supplement its approved ANDA to provide for an OTC product. However, if the innovator firm received 3-year exclusivity, the generic firm would be forced off the market until exclusivity expiration, despite having an approved ANDA for a prescription product. Finally, the marketing and distribution of an OTC product could present new challenges for many generic firms that have no experience competing in this market, which is dominated by private label products marketed by large retail pharmacy chains.

505(b)(2) NDAs

Section 505(b)(2) of the FDC Act, added as part of the Hatch–Waxman Amendments, authorizes an NDA where some of the safety or effectiveness investigations required to support NDA approval were not conducted for the applicant, and for which the applicant has not obtained a right of reference or use.§ A 505(b)(2) NDA is, in essence,

* *Biovail Corporation v. U.S. Food and Drug Administration*, 519 F. Supp. 2d 39 (D.D.C. 2007) (involving bupropion).
† 21 USC § 355-1(f) (added by FDAAA).
‡ 21 CFR § 310.200(d).
§ 21 USC § 355(b)(2).