

allowed ANDA sponsors to seek approval for generic version of the tablet product, although the innovator tablet product was no longer being marketed. FDA's decision was upheld by a court, which stated that FDA's determination that the withdrawal was not for safety or effectiveness reasons was, in the first instance, within FDA's discretion.*

"MOVING TARGET" AND DISAGREEMENTS WITH THE FDA

A longstanding industry complaint with the FDA premarket approval process (not limited to generic drugs, by any means) is the so-called "moving target," in which product sponsors satisfy what they believe were the applicable requirements, only to be told that the requirements have changed or that additional requirements are now applicable. In an effort to address this longstanding concern, FDAMA amended the FDC Act in 1997 to provide for a binding presubmission conference for both NDAs and ANDAs. Assuming written agreement is reached, the agreement is not to be changed after testing begins, except with the sponsor's consent or based on an FDA determination that a new, substantial scientific issue essential to the safety or effectiveness of the drug has been identified.† In practice, the provision has been of limited use. With regard to ANDAs, it applies only to agreements on the design and size of bioavailability and bioequivalence studies. Even within that limited scope, few prospective ANDA sponsors have reached written agreements with the FDA regarding study design.

Disagreements with the FDA staff over scientific or technical issues can be appealed up through the chain of command.‡ At least in theory, appeals could continue up to the FDA Commissioner. If a disputed scientific or technical issue regarding a pending ANDA or 505(b)(2) NDA cannot be resolved through the appeals process, judicial review is usually not a realistic option. Before seeking judicial review, a drug sponsor generally must utilize the administrative process for challenging FDA's decision that its application will not be approved. This procedure calls for a formal evidentiary hearing before FDA's Administrative Law Judge (ALJ), an initial decision by the ALJ, and a final agency decision by the FDA Commissioner or his or her delegate. Only then is judicial review available.§ Unfortunately for industry, this administrative process is unlikely to result in a satisfactory decision on the merits for the drug sponsor. Moreover, it is very time consuming and is likely to take a number of years to run its course. Thus, as a practical matter, it has very seldom been used by industry. In some cases, it may be possible to characterize an ANDA or 505(b)(2) NDA dispute in "legal" terms, thereby increasing the chance of obtaining judicial review without first resorting to the administrative hearing process.

Finally, in some cases, ANDA and 505(b)(2) NDA sponsors will discover that they have relied on agency advice that is subsequently repudiated. In general, such

* *Somerset Pharmaceuticals, supra*, n. ¶¶, p. 351.

† 21 USC § 355(b)(5) and (j)(3).

‡ 21 USC § 360bbb-1; 21 CFR § 10.75.

§ 21 USC § 355(j)(5)(E), (c)(1)(B), and (h).