an innocent applicant will have to bear the brunt of FDA's error.* Judicial relief is generally not available.†

Application Approval Delays

Although Hatch–Waxman Amendments provide that the FDA will approve or disapprove a 505(b)(2) NDA or ANDA within 180 days,‡ the median ANDA approval time is, as of this writing, more than 30 months. One early court challenge to compel the FDA to review a sponsor's ANDAs in timely fashion was rejected.§ However, in another case, a district court ordered the FDA to render a decision (either approve or refuse to approve) a 505(b)(2) NDA.¶ The FDA initially appealed but subsequently withdrew its appeal and approved the application. This decision probably should be viewed as one involving unique facts, including the passage of a substantial length of time during which the FDA had failed to take any action on the pending application and FDA's letter to the sponsor in which the agency indicated that the review was complete but the agency could not, in essence, make up its mind.

Much of the delay in reviewing and approving ANDAs can be attributed to the successful Prescription Drug User Fee Act (PDUFA), which requires drug sponsors to pay user fees in connection with NDAs for prescription drugs. The user fee legislation includes a commitment by the FDA that it will review and take action on 90% of all complete original applications and supplements within 10 months of receipt. The user fee legislation has had the practical effect of diverting agency resources that would otherwise have been used for the review of ANDAs to the innovator product side of the FDA's Center for Drug Evaluation and Research.

Many in the generic drug industry believe that generic drug user fees would help alleviate the delay in reviewing and approving ANDAs. The FDA has charged user fees for innovator drug NDAs (including 505(b)(2) NDAs) since 1992 and more recently for medical device premarket approvals and 510(k) ("substantial equivalence") determinations, innovator animal drug applications, and generic animal drug applications. Different segments of the generic drug industry have debated the wisdom of generic drug user fees for over a dozen years. As of the time of this writing, it appears that legislation will be enacted to establish generic drug user fees starting with fiscal year 2013 (beginning October 1, 2012). As with PDUFA, this legislation would include FDA commitments to meet performance goals. Legislation would also address the backlog of pending ANDAs and supplements.

The FDA's Office of Generic Drugs has a medical affairs staff that is able to address some—but no means all—"medical" issues that sometimes arise in connection with ANDAs. Examples of such ANDAs include modified-release products with complex bioequivalency issues and nonsystemically absorbed drug products where a

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* See, e.g., FDA May 25, 2011 letter at 17–18, *supra*, n. *, p. 353 (involving subsequently repudiated FDA advice recommending a 505(b)(2) NDA, rather than an ANDA, for a generic colchicine drug product).

† *Purepac Pharmaceutical Company*, *supra*, n. **, p. 340 (involving erroneous FDA advice on how to address an Orange Book patent).

‡ 21 USC § 355(j)(5)(A) and (c)(1).

§ *In re Barr Laboratories, Inc.*, 930 F.2d. 72 (D.C. Cir. 1991).

¶ *Sandoz, Inc. v. Leavitt*, 427 F. Supp.2d 29 (D.D.C. 2006) (involving somatropin).