FDAMA § 116

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105-115). Section 116 of FDAMA amended the Federal Food, Drug, and Cosmetic Act (The Act) by adding section 506A (21 U.S.C. 356a), which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes. Section 116 further provides that these requirements take effect upon the effective date of regulations promulgated to implement section 116 or 24 months after enactment of this provision, whichever occurs first.

On June 28, 1999, FDA published in the *Federal Register* a proposed rule revising 21 CFR 314.70 (64 FR 34608) and a notice of availability of a draft companion guidance entitled *Changes to an Approved NDA or ANDA* (64 FR 34660). The proposed rule, when finalized, is intended to implement section 506A, and the guidance is intended to provide the Agency's current thinking on how it will apply the requirements of this section. Comments are requested by September 13, 1999, on the proposed rule and August 27, 1999, on the guidance. Because the comment period for the proposed rule does not close until September 13, 1999, FDA does not expect a final rule revising 21 CFR § 314.70 to be published before November 21, 1999.

How will CDER manage postapproval manufacturing changes through November 20, 1999?

> Up to and including November 20, 1999, the current regulations at § 314.70 will govern postapproval manufacturing changes. On November 21, 1999 these regulations will be replaced by the provisions of section 506A.

How does CDER intend to manage postapproval manufacturing changes after November 20, 1999?

> After November 20, 1999, and until the final regulation for § 314.70 publishes, section 506A will be the sole basis for FDA's regulation of postapproval manufacturing changes for products approved in new drug (NDA) or abbreviated new drug (ANDA) applications.

FDA intends to issue a final guidance on *Changes to an Approved NDA or ANDA* before November 21, 1999. The guidance, published in draft on June 28, 1999, will have been revised as appropriate based on the public comments and will represent FDA's current thinking on how it will apply the requirements of section 506A of the Act for NDA and ANDA products.[1] FDA will later revise the guidance on *Changes to an Approved NDA or ANDA* to make it consistent with the final rule for § 314.70. FDA intends to publish the revised guidance at the same time it publishes the final rule.

[1] This guidance provides recommendations for human drugs other than specified biotechnology and specified synthetic biological products. Recommendations for reporting categories for changes relating to specified biotechnology and specified synthetic biological products regulated by CDER are found in the guidance for industry entitled *Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products* (July 1997).