Freedom of Information Act

Under a longstanding FDA regulation, a summary of the safety and effectiveness data and information that support a drug approval is "immediately" available for public disclosure after NDA approval, with very limited exceptions.* These documents are often very useful to sponsors and prospective sponsors of ANDAs and 505(b)(2) NDAs. In practice, however, the public availability of a data summary, often referred to as an "SBA" or a "summary basis of approval," varies widely.

The FDAAA amended the FDC Act to address this situation.† The FDA is now required to post the "action package" (including labeling, a review summary, and the "decision document") for approval of a NDA drug or a biological on its website within 30 days after approval if the approval involves a new active ingredient and within 30 days after the third FOIA request for the documents for any other NDA drug or biological. In addition, the FDA is required to post on its Internet site a "summary review" within 48 hours after approval, unless the FDA needs additional time for the redaction of nondisclosable information. Although 505(b)(2) NDAs are within the scope of the new provision, the new provision does not affect the public availability of information regarding the approval of ANDAs.

Clinical Trials Registry

In 2007, the FDAAA amended the Public Health Service Act to add requirements for registering "clinical trials," other than Phase I trials, with the National Institutes of Health (NIH).‡ In relevant part, notice of covered clinical studies must be submitted to the NIH for listing on an NIH website. At the time of ANDA or 505(b)(2) NDA submission, a certification regarding compliance with the clinical trials registry requirements (Form FDA 3674) must be submitted.§

The scope of the registry requirement is arguably ambiguous. In light of this uncertainty, the generic industry asserted that the inclusion of in vivo bioequivalency studies within the scope of the reporting requirement was never intended by Congress and that the public availability of this information would adversely affect the business practices of most generic drug firms. Possibly in response to these views, the FDA posted a draft "definitions" document on the NIH website that takes the position that typical ANDA biostudies that measure drug levels in blood or other bodily fluids are outside the scope of the registry and certification requirements; however, a comparative clinical trial used to measure bioequivalence is subject to the new requirements.¶

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* 21 CFR § 314.430(e)(2).

† 21 USC § 355(l) (as amended by FDAAA).

‡ 42 USC § 282(j) (added by FDAAA).

§ *Guidance for Sponsors, Industry, Researchers, Investigators, and Food and Drug Administration Staff, Certifications to Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act*, January 2009. Available at http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0224-GDL.pdf. Accessed June 13, 2013.

¶ http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf. Accessed June 13, 2013.