SHEPPARD MULLIN
SHEPPARD MULLIN RICHTER & HAMPTON LLP
FDA Law Update BLOG
Current Issues Affecting FDA-Regulated Companies

FDA Law Update

Posted at 6:39 AM on March 11, 2010 by Sheppard Mullin

FDA Proposed Rule: Sponsors Must Report Suspicions of Falsified Study Data

A proposed FDA rule would require all "sponsors" (defined broadly) to report not only *known* falsification of study data but also falsifications merely *suspected*. The rule, "Reporting Information Regarding Falsification of Data," defines falsification as "creating, altering, recording, or omitting data in such a way that the data does not represent what actually occurred." The rule proposes strict timeframes for reporting. The duty to report would be undiminished even where evidence of falsification is slight.

Parties seeking to comment on the proposed rule must submit comments by May 20, 2010.

Broadly Defining "Sponsor"

The proposed rule would include petitioners submitting food additive, color additive, nutrient content claim, and health claim petitions; manufacturers or distributors submitting new dietary ingredient notifications; and sponsors as defined in §§ 58.3(f) (non-clinical laboratory studies), 312.3(b) (clinical investigations), 510.3(k) (animal drugs), and 812.3(n) (investigational device exemptions). The Agency says this broad definition of "sponsor" is needed to prevent ambiguities.

Falsfications by Whom, and When?

Sponsors would report a finding or suspicion that *any* person has engaged in falsification in reporting of study results. Similarly, reports would be required for falsification during the course of proposing, designing, performing, recording, supervising, or reviewing studies that involve human subjects or animal subjects. The rule would cover falsifications discovered or suspected before, during or *after* study completion, as well as after review, approval, or authorization of the affected product or labeling.

Suspected Falsification

The proposed rule would require sponsors to report suspected falsification. Sponsors need not make definitive determinations of falsification prior to reporting, but they cannot avoid making a report of suspicion merely for lack of evidence. The Agency has declined to set a specific evidentiary threshold. "Rather, a sponsor would be required to report information of which it is

aware suggesting that a person has, or may have, engaged in the falsification of data in connection with studies conducted by, or on behalf of, the sponsor, or relied on by the sponsor. This reporting obligation would exist regardless of the amount of evidence…." 33 Fed.Reg. 7415 (Feb. 19, 2010).

Timeframe for Reporting

Sponsors must report no later than 45 days after becoming aware of the falsification. In the case of suspected falsification, it is unclear whether the 45-day period is delayed for purposes of further investigation or whether satisfactory further investigation would relieve a sponsor's obligation.

Information Included in Such Reports

Reports must include the name of the person suspected or confirmed to have engaged in falsification, and his or her address and phone number. The sponsor must identify the potentially affected study and, if applicable, information about the drug or device application. In addition, the sponsor must provide the information that led to the suspicion. FDA is considering whether reports should include additional information, such as the National Clinical Trail (NCT) number.

Reports can be made to the appropriate FDA center via telephone, facsimile, mail, or electronic mail. FDA will determine whether to investigate further.

Penalties

The Agency has not yet determined appropriate penalties. Under consideration: Making failure-to-report a violation of section 301(e) of the Federal Food, Drug, and Cosmetic Act (i.e., failure to make a required report); or a violation of 18 U.S.C. 1001, submission of a false statement to the government.

Reminder: comments must be submitted by May 20, 2010.

Authored by:

Deborah M. Shelton
(202) 772-5351
dshelton@sheppardmullin.com

and

Arianna B. Chernove
(202) 772-5361
achernove@sheppardmullin.com