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FDA Proposed Rule Requires Reporting Suspected Falsification of Data in Studies with Human or Animal Subjects

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The U.S. Food and Drug Administration (FDA or the Agency) recently announced a Proposed Rule titled "Reporting Information Regarding Falsification of Data" in a February 19 *Federal Register* Notice (75 Fed. Reg. 7,412). FDA is proposing to require makers of FDA-regulated products to report confirmed or suspected falsification of data in studies involving human or animal subjects to the Agency within 45 calendar days of becoming aware of such information. FDA is requesting general comments on the Proposed Rule and the following six specific issues:

- The definition of "falsification of data"
- The time frame for reporting
- Whether regulations related to marketing applications should be amended to require applicants to report possible falsification of data
- Whether the proposed rule should specify an evidentiary standard or threshold for reporting
- Whether to include additional descriptions of "errors" excluded from the proposed reporting requirements
- The information that should be provided to FDA in a report, and whether the regulations should specify what information must be reported

Comments on the Proposed Rule must be submitted to the FDA docket by the May 20, 2010 deadline (Docket No. FDA-2008-N-0115, available at http://www.regulations.gov).

Who Will Be Affected

The Proposed Rule affects the conduct of FDA-regulated research and the submission of information in support of applications and petitions for FDA product approvals of certain labeling claims, including the following:

- Good Laboratory Practice (GLP) for nonclinical laboratory studies
- Color additive petitions
- Petitions for nutrient content claims and petitions for health claims
- Premarket notifications for a Food Contact Substance (FCS)

- Human and animal food additive petitions
- Dietary supplements
- Investigational New Drug Applications (INDs)
- Investigational Device Exemptions (IDEs)
- New animal drugs for investigational use

It is important to note that FDA is not proposing to amend its regulations for New Drug Applications (NDAs), Biologic License Applications (BLAs), Premarket Approval Applications (PMAs) and Establishment Registration and Device Listings (including 510(k) premarket notifications) for medical devices, or New Animal Drug Applications at this time, as the Agency recognizes that "the applicant is not always the sponsor for a given study and that arrangements between sponsors and applicants can sometimes be complex." However, FDA is requesting comments on whether nonsponsor applicants (e.g., an applicant that did not sponsor a study but acquired the rights to the study data from the original sponsor) should be required to comply with the Proposed Rule.

When the Rule Will Apply: What and When to Report to FDA

FDA is proposing to require sponsors to submit information indicating that any person has, or may have, engaged in the falsification of data in reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies that involve human subjects (e.g., clinical investigations) or animal subjects (e.g., nonclinical laboratory studies and clinical studies in animals) conducted by or on behalf of a sponsor or relied on by a sponsor. The information on data falsification should be submitted to the appropriate FDA Center promptly, but no later than 45 calendar days after the sponsor becomes aware of the information.

The proposed requirement would be ongoing and cover the periods before and after a study's completion, including after the review, approval, or authorization of the affected product or labeling. Importantly, the reporting obligation would apply not only to confirmed falsification but also to possible or suspected falsification, does not have a minimum information threshold, and would exist regardless of the amount of evidence, if any, the sponsor has with regard to the intent of the person who has, or may have, falsified data.

The Proposed Rule defines "falsification of data" as "creating, altering, recording, or omitting data in such a way that the data do not represent what actually occurred" and lists the specific examples, including making up or altering data such as laboratory measurements, reporting of a nonexistent study subject, forging a signature on an informed consent form, omitting exclusionary medical history, and omitting data from a statistical analysis. The Proposed Rule specifically excludes unintentional errors in recording and reporting information from the reporting requirement. In addition, plagiarism will not have to be reported because it is outside the scope of FDA compliance oversight.

Importantly, the Proposed Rule would apply "not only to data from studies conducted by a sponsor, but also to data from studies not sponsored or conducted by a sponsor but cited in a petition, new dietary ingredient notification, or application to FDA in support of a claim, product marketing, or other regulatory action such as reclassification of a device."

The Agency is considering whether the regulations should specify what information about possible falsification must be reported to FDA. A sponsor may provide this information by any means, including telephone, mail, electronic mail, or facsimile.

Possible Implications of the Rule

Under the Proposed Rule, FDA would determine whether further Agency investigation is warranted based on the reported information "in conjunction with other information available to [it]," and these investigations, in turn, "might form the basis of administrative or enforcement actions, such as excluding clinical trials from consideration by FDA, placing a clinical trial on hold, or initiating disqualification of investigators or criminal proceedings."

Failure to report possible falsification of data might constitute a violation of Section 301(e) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 331(e)) (concerning failure to make a required report) or 18 U.S.C. § 1001 (concerning the submission of a false statement to the federal government).

The Proposed Rule raises additional issues for consideration, such as:

- Whether FDA has the statutory authority to require such reports
- Whether FDA will submit information obtained from the sponsors to other government agencies, for example the Department of Justice
- Whether the states and public will have access to the information submitted to FDA
- Whether FDA will articulate standards for determining the compliance status of studies a company has acquired and did not sponsor or conduct.

FDA says that the Proposed Rule "does not intend to impose any additional monitoring responsibilities" and is not expected to have a significant economic impact on reporting companies. However, because of new reporting obligations and penalties for noncompliance, the Proposed Rule is likely to increase the scope and cost of auditing and monitoring nonclinical and clinical studies, and the conduct and cost of due diligence for product acquisition. In addition, sponsors will have to consider inclusion of appropriate representations in contracts with service providers of clinical and nonclinical study services, which may result in protracted contract negotiations and an increase in the cost for the services.

Please contact either of the following Morgan Lewis attorneys for additional information on the Proposed Rule or for assistance with preparation or review of comments to FDA:

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