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Client Alert

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FDA Issues Draft Guidance on Reporting Drug Sample Distribution Information under the Patient Protection and Affordable Care Act

On March 28, 2012, the Food and Drug Administration ("FDA" or "Agency") announced the availability of a draft guidance for industry titled "Compliance Policy on Reporting Drug Sample Distribution Information Under the Affordable Care Act" ("Draft Guidance"). The Draft Guidance is intended to provide information regarding the Agency's implementation of the drug sample transparency reporting requirements set forth in section 6004 of the Patient Protection and Affordable Care Act ("PPACA").

Section 6004 of the PPACA requires that prescription drug manufacturers and authorized distributors of record ("ADRs") submit certain drug sample information to the U.S. Department of Health and Human Services no later than April 1 of each year, beginning on April 1, 2012. In substance, the Draft Guidance provides that:

1. FDA does not intend to object until at least October 1, 2012, if manufacturers and ADRs do not submit the required drug sample information on April 1;
2. The Agency intends to provide notice before revising its exercise of discretion with respect to compliance;
3. If manufacturers and ADRs wish to comply with section 6004 by April 1, they may do so using FDA's Electronic Submissions Gateway; and
4. Click on the following link for detailed instructions for submitting drug sample information via the Gateway.

FDA's notice announcing the availability of the Draft Guidance states that the Agency expects to issue further draft guidance concerning the drug sample reporting requirements later in 2012.

Given that the U.S. Supreme Court heard oral arguments on the constitutionality of the PPACA earlier this week, companies may wish to consider waiting until after the Court issues its decision, which is expected in June, before expending resources complying with section 6004. Interested parties may submit comments on the Draft Guidance by June 4, 2012.

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