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Client Alert

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FDA Issues Draft Guidance Staying Enforcement of Sample Reporting

On April 3, 2012, the Food and Drug Administration (FDA) issued a much-awaited announcement that the agency would exercise its enforcement discretion regarding the drug sample reporting requirements mandated under Section 6004 of the Affordable Care Act (ACA). The draft guidance for industry, entitled "Compliance Policy on Reporting Drug Sample Distribution Information," states that the FDA will not object until at least October 1, 2012, if manufacturers and authorized distributors delay submitting information on drug sample distribution as required by statute.[1] In addition, the FDA confirmed that it would provide notice before revising the policy to exercise enforcement discretion in this area.

Although the ACA required manufacturers and authorized distributors to provide an annual drug sample report to FDA by April 1, 2012, the FDA did not provide additional guidance on the drug sample reporting process until the draft guidance was issued. In addition, the agency noted that additional time was required to allow for efficient use of the electronic Gateway as the preferred method for submissions, considering the anticipated volume to be received. The current electronic Gateway system allows for drug sample submissions, if a manufacturer or distributor should choose to comply with section 6004. An "ACA 6004 Drug Sample" option will be available on the Gateway submission page, and technical requirements are outlined in "ACA Industry Submission Specifications User Guide," posted on the FDA's webpage. [2]

Pursuant to the ACA, the following information on drug sample distribution should be submitted to the FDA on an annual basis:

- the identity and quantity of drug samples requested;
- the identity and quantity of drug samples distributed;
- the name, address, professional designation, and signature of any person who makes or signs for the request; and
- any other category of information determined appropriate by the secretary.

1 Available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM297848.pdf?utm_source=fdaSearch&utm_medium=website&utm_term=section 6004&utm_content=1.
2 Available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM297610.pdf.

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Comments on the draft guidance need to be submitted by June 4, 2012, to be considered by the agency in any final guidance document.