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Client Alert

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FDA Guidance Provides Notice that Newly Marketed Unapproved Products May Be Subject to Immediate Enforcement Action

On September 19, 2011, the U.S. Food and Drug Admnistration (FDA) published a revision of the agency's June 2006 guidance document, entitled *Marketed Unapproved Drugs—Compliance Policy Guide Sec. 440.100, Marketed New Drugs Without Approved NDAs or ANDAs*.[1] The revised guidance document reaffirms the agency's risk-based enforcement approach and enforcement priorities for unapproved drug products and provides notice to drug companies that any unapproved drug products brought to market on or after September 19, 2011, will be subject to immediate enforcement action.[2]

While the FDA states that public comment is welcome at any time, the revised guidance document is effective immediately. For unapproved new drugs released on or after September 19, 2011, the FDA may take enforcement action at any time, without regard to the enforcement priorities outlined in the revised guidance document and without prior notice. The FDA also notes that it does not intend to allow any grace period for continued marketing for any newly marketed unapproved drug products, although the agency will continue to make case-by-case determinations whether continued marketing for some period of time is justified for other unapproved products (i.e., those unapproved products on the market prior to September 19, 2011).

In a related press release, the FDA notes that the revised guidance is, in part, the agency's response to the steady influx of unapproved new drugs to market. Despite the agency's efforts since 2006 to use an orderly approach to remove unapproved drugs from the market, the FDA has noted that new unapproved drugs continue to be introduced on the market for several reasons. For instance, other drug companies may attempt to take advantage of perceived market share opportunities that arise after the agency removes an unapproved drug from the market. Also, absent a public announcement about future enforcement action, new unapproved drugs may be released to compete with other unapproved drugs already on the market.

1 See 76 Fed. Reg. 58398 (Sept. 21, 2011).
2 The revised guidance document is available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf.

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