

Monthly summary of industry news

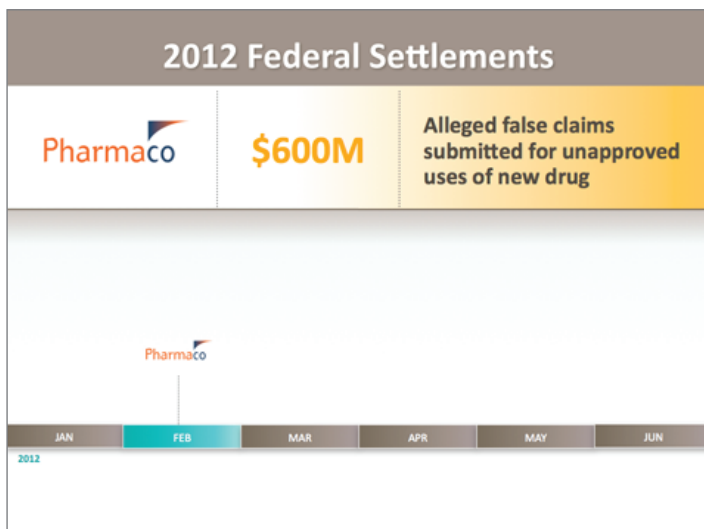
Potomac's monthly news summaries help you cut through the clutter and stay current on key compliance events. The news summaries are provided in an appealing format reflecting your organization's branding and ready for immediate distribution to the Board, senior management or Compliance Committees:

- Monthly Headlines
- Key Summaries and Implications
- Original Source Links

Can't wait until next year?


Potomac delivers personalized Mid-Year-in-Review Presentations, covering highlights from the end of January through early July* in a similar multimedia format as our annual Year-in-Review:

- Settlement Updates
- Multimedia inserts
- Key Headlines
- Branded to your company
- New Guidelines & Regulations
- Inclusion of your logo




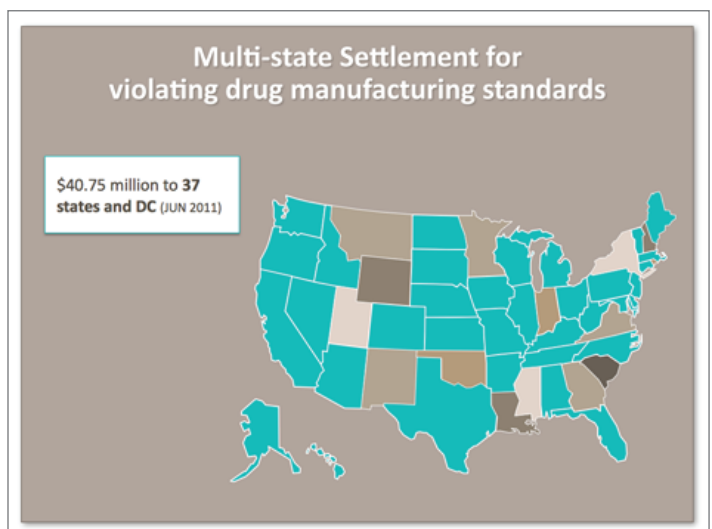
Compliance News

Headline
FDA Issues Revised Guidance on Unapproved Drugs



Summary
 The FDA issued a revision to its 2006 guidance titled "Marketed Unapproved Drugs- Compliance Policy Guide Sec. 440.100, Marketed New Drugs Without Approved NDAs or ANDAs." This revised guidance clarifies that any unapproved new drug introduced onto the market after September 19, 2011 will be subject to immediate enforcement action, without prior notice and without regard to the enforcement priorities set out in the guidance.

Source:
<http://www.fda.gov/Drugs/Guidance/Compliance/Regulatory/Information/Enforcement/ActivitiesbyFDA/SelectedEnforcementActions/UnapprovedDrugs/ucm270531.htm>

* Targeted delivery on July 15th with specific coverage dates determined by client and year