

Porzio Compliance Digest: Enforcement Action Databases

The federal government's intensified scrutiny of life sciences companies has increased the demands on today's compliance professionals.

To aid our customers in recognizing and understanding the significance of trends in government enforcement and inspections, Porzio Pharmaceutical Services is pleased to expand our Porzio Compliance Digest with three new Enforcement Action Databases.

The **OPDP Promotional Violations Database** contains searchable untitled and warning letters issued to life sciences companies by the FDA's Office of Prescription Drug Promotion. By categorizing letters in a variety of ways, we have empowered users to search the letters by date of issuance, type of promotional material, and identified violation.

This database contains copies of issued letters and associated materials, when available. Subscribers may search for specific letters and related violations, allowing for an accurate assessment of trends in prescription drug advertising and promotional labeling enforcements.

The **FDA PDMA Inspections Database** contains data on Established Inspection Reports related to Prescription Drug Marketing Act inspections. Based on documentation acquired from government agencies, we have catalogued and synthesized violations noted in these reports. Subscribers access relevant elements through an easily searchable format, which categorizes data by violation, inspector, and areas of inspection.



[OPDP Promotional
Violations Database](#)

[FDA PDMA Inspections
Database](#)

[Government
Prosecutions Database](#)



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The **Government Prosecutions Database** outlines federal government actions against life sciences companies that have allegedly violated, among others, anti-kickback laws, FDA regulations, the PDMA and the False Claims Act.

Subscribers access corporate integrity agreement (CIA) summaries, which describe the evolving compliance requirements of life sciences companies. The summaries are supplemented with relevant documents. This database is searchable by CIA year and obligation, alleged violation, risk area, and product type. Through this database, subscribers gain valuable insight into the violations most often pursued by the federal government.

Call us today to strengthen your compliance program with the Porzio Compliance Digest.

About Porzio

For more than 30 years, the law firm of Porzio, Bromberg & Newman P.C. has provided regulatory counseling, risk management and litigation avoidance counseling to pharmaceutical, biotechnology and medical device manufacturers. Our experience and dedication to the life sciences industry led us to create Porzio Pharmaceutical Services, LLC (PPS).



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