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FDA Deskbook: A Compliance and Enforcement Guide Promotion and Marketing of Prescription Drugs, Biologics, and Devices; and Appendix 18A Author(s): Dara Katcher Levy, Jeffrey N. Wasserstein, Sara W. Koblitz Practice Area: Corporate & Securities, Health Care Published: May 2016 Supplement Date: Nov 2019 PLI Item #: 173127

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Compliance & Enforcement (Food) | FDA

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FDA and DEA Litigation Briefing

FDA Deskbook: A Compliance and Enforcement Guide September 26, 2016; Quantum of Effectiveness Evidence in FDA's Approval of Orphan Drugs: Update, July 2010 to June 2014, Therapeutic Innovation & Regulatory Science April 27, 2015; Bringing Your Pharmaceutical Drug to Market April 1, 2015

James E. Valentine | Hyman, Phelps & McNamara, P.C.

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The case concerned interactions with pharmacies regarding Myfortic, a drug that prevents kidney rejection in transplant patients, and Exjade, a drug that treats chronic iron overload. The case proceeded through fact and expert discovery and pre-trial submissions before resolving with the federal and state governments prior to trial.

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