

### Drug Products That Have Been Withdrawn from the U.S. Market

Since 2000, the U.S. Food and Drug Administration has approved nearly 300 new drug applications and biologics license applications for new molecular entities. In the same time period, a few new drugs were withdrawn from the market by the manufacturers, typically in close consultation with FDA. The table below lists many of the approved new drugs that were withdrawn from the U.S. market from 2000 to present and as to which there is public information suggesting the decision was made on the basis of safety or efficacy concerns. (It is not a comprehensive list.)

Drug Trade Name	Reason for Withdrawal
Xigris	In an October 25, 2011 press release, Eli Lilly and Company announced withdrawal of Xigris(R) “in all markets following results of the PROWESS-SHOCK study, which showed the study did not meet the primary endpoint of a statistically significant reduction in 28-day all-cause mortality in patients with septic shock. The company is working with regulatory agencies on this withdrawal, and is in the process of notifying health care professionals and clinical trial investigators.” <i>Lilly Announces Withdrawal of Xigris® Following Recent Clinical Trial Results</i> , Press Release, October 26, 2011.
Meridia	An FDA News Release stated that, “Abbott Laboratories has agreed to voluntarily withdraw its obesity drug Meridia (sibutramine) from the U.S. market because of clinical trial data indicating an increased risk of heart attack and stroke.” <i>FDA News Release, Oct. 8, 2010</i> .
Darvon/Darvocet	FDA stated that, “FDA notified healthcare professionals that Xanodyne Pharmaceuticals has agreed to withdraw propoxyphene, an opioid pain reliever used to treat mild to moderate pain, from the U.S. market at the request of the FDA, due to new data showing that the drug can cause serious toxicity to the heart, even when used at therapeutic doses.” <i>FDA News Release: Propoxyphene: Withdrawal - Risk of Cardiac Toxicity, posted November 19, 2010</i> .
Mylotarg	FDA stated that, “Pfizer Inc. today announced the voluntary withdrawal from the U.S. market of the drug Mylotarg (gemtuzumab ozogamicin) for patients with acute myeloid leukemia (AML), a bone marrow cancer. The company took the action at the request of the U.S. Food and Drug Administration after results from a recent clinical trial raised new concerns about the product’s safety and the drug failed to demonstrate clinical benefit to

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	patients enrolled in trials.” <i>FDA News Release: Pfizer Voluntarily Withdraws Cancer Treatment Mylotarg from U.S. Market, June 21, 2010.</i>
Trasylol	In “November [2008], FDA requested that Bayer stop marketing Trayslol [] based on preliminary results from the BART trial.” Results from the BART trial confirmed prior safety concerns, “showing that Trasylol is associated with an increased risk of death compared to other antifibrinolytics [].” Brian Marson, <i>Trasylol Death Knell: Bayer Withdraws Remaining Product from U.S. Market</i> , The Pink Sheet, May 19, 2008, at Vol. 70 No. 20.
Raptiva	Genentech “announced April 8 that it will pull Raptiva permanently from the market as of June 9 due to the drug’s risk of causing [a] life-threatening brain infection [].” <i>Raptiva Withdrawal Shows Comparative Safety Focus From New, Decisive FDA</i> , The Pink Sheet, April 13, 2009, at Vol. 71, No. 15.
Permax	An FDA Public Health Advisory dated March 29, 2007 states that “companies that manufacture and distribute pergolide have agreed to withdraw the drug from the market” and that “[r]esults of two new studies showed that some patients with Parkinson’s disease treated with pergolide had serious damage to their heart valves when compared to patients who did not receive the drug.” <i>FDA Public Health Advisory - Pergolide (marketed as Permax)</i> , March 29, 2007.
Zelnorm	In a March 30, 2007 Press Release, Novartis stated that it was “complying with a request from the [FDA] to suspend US marketing and sales of Zelnorm [] after Novartis notified the FDA about a retrospective analysis of data from more than 18,000 patients in the clinical trial database.” An analysis of the clinical database revealed a “statistically significant imbalance in the incidence of cardiovascular ischemic events in patients taking Zelnorm compared to those taking placebo.” <i>Novartis Suspends US Marketing and Sales of Zelnorm(R) in Response to Request from FDA</i> , Press Release, March 30, 2007.
NeutroSpec	The FDA “issued a Public Health Advisory to alert health care providers that the agency has requested the market withdrawal of the diagnostic imaging agent NeutroSpec [Technetium (99m TC) Fanolesomab] pending further review of reported deaths and serious and life-threatening adverse events associated with use of the product.” <i>FDA News Release December 19, 2005.</i>
Palladone	An FDA News Release dated July 13, 2005 stated that “[a]fter acquiring new information that serious and

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	potentially fatal adverse reactions can occur when Palladone (hydromorphone hydrochloride) extended release capsules are taken together with alcohol, the U.S. Food and Drug Administration has asked Purdue Pharma L.P., the makers of the drug, to withdraw it from the market. <i>FDA News Release: FDA Asks Purdue Pharma to Withdraw Palladone for Safety Reasons</i> , July 13, 2005.
Bextra	FDA “has requested that Pfizer voluntarily withdraw Bextra from the United States market. Pfizer has agreed to suspend sales and marketing of Bextra in the United States, pending further discussion with the Agency. At this time, the Agency has concluded that the overall risk versus benefit profile of Bextra is unfavorable.” <i>FDA Alert</i> , April 7, 2005.
Vioxx	Merck & Co., Inc. “announced a voluntary withdrawal of Vioxx (rofecoxib) from the U.S. and worldwide market due to safety concerns of an increased risk of cardiovascular events (including heart attack and stroke) in patients on Vioxx.” <i>FDA Public Health Advisory: Safety of Vioxx</i> , September 30, 2004.
Orlaam	Roxane “will discontinue the sale and distribution of [Orlaam]” and “said it no longer believes that the benefits of the product outweigh the risks in the face of less toxic treatment alternatives.” <i>Roxane Orlaam Discontinued; Suboxone Approval Cited as Reason</i> , The Pink Sheet, September 8, 2003, at Vol. 65, No. 36, Pg. 21.
Baycol	“The injectable anesthetic is being voluntarily withdrawn from the market by Organon following five deaths.” <i>Raplon Bronchospasm AES within Labeled Incidence; Drug Withdrawn</i> , The Pink Sheet, April 2, 2001, at Vol. 63; No. 14; Pg. 34
Raplon	“Raplon was withdrawn from the market after five deaths were associated with the product over a three year period.” <i>CDER Deputy Galson Brings Risk Management Experience to FDA Surveillance</i> , The Pink Sheet, April 2, 2001, at Vol. 63; No. 14; Pg. 35.