

# Recent Withdrawals

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- Seldane™ (terfenadine) 2/98
- Posicor™ (mibefradil) 6/98
- Duract™ (bromphenac) 6/98
- Hismanal™ (astemizole) 6/99
- Roxar™ (grepafloxacin) 11/99
- Propulsid™ (cisapride) 3/23/00
- Rezulin™ (troglitazone) 3/21/00
- Lotronex™ (alosetron HCl) 8/24/00
- Raplon™ (rapcuronium) 3/01
- Baycol™ (cerivaxtatin) 8/8/01
- Vioxx™ (rofecoxib) 9/30/04

*92 NME's from 1998-2000*

# Rezulin Withdrawal

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*“FDA took this action after its review of recent safety data...showed that Rezulin is more toxic to the liver than the other two drugs”*  
[HHS News, 3/21/00]

*“And we’ve had to withdraw drugs from the market that would have been safe if used according to label instructions”* [Janet Woodcock, Temple University, 4/4/00]

*Not to mention the “pain” in the pain reliever market*

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  - Miscellaneous
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## ELI LILLY, PFIZER, AND GLAXOSMITHKLINE (ANTI-DEPRESSANT MANUFACTURERS)

**Amount At Issue:** No Amount Specified    **Date Added to Site:** 9/19/2001

**Commonly-Prescribed Antidepressants Are Extremely Dangerous for Some**

Some 200 legal actions have been filed against Eli Lilly, Pfizer, and GlaxoSmithKline, the manufacturers of Prozac (fluoxetine), Zoloft (sertraline), and Paxil (paroxetine), respectively, to recover for suicides or homicides--some completed, some only attempted--by patients in the first few days or weeks after they were prescribed one of these drugs.

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I want to get the Eli Lilly, Pfizer, and GlaxoSmithKline (anti-depressant manufacturers) case, a \$9.99 value, FREE with my trial charter membership to ClassActionAmerica.com. In addition to getting:

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- Easy-to-read Full Description of the Class Action Lawsuit
- How to Qualify for Money Due\*
- How to Make a Claim\*
- Who to Contact Including Name, Address, Phone, & Website



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- IDENTITY THEFT
- MORTGAGE
- METABOLIFE
- NINTENDO
- PRESCRIPTION


**DRUGS**

- ACUTANE
- ALBUTEROL
- ANTIDEPRESSANTS
- ARAVA
- AVANDIA
- BAYCOL
- BEXTRA
- ENBREL
- FEN-PHEN
- LOTRONEX
- MERIDIA
- OXYCONTIN
- PPA
- PERMAX
- PREMPRO
- PROPULSID
- REMICADE
- REZULIN
- SERZONE
- VIOXX

**FRAUD**

- WHISTLEBLOWER

**Top 20**



# FDA RM Guidances

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- Concept Papers, March 2003
- Hearings April 2003
- Draft Guidances, May 2004
- Final Guidances, March 2005
  - Premarketing Risk Assessment
  - Development and Use of Risk Minimization Action Plans (RiskMAPs)
  - Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

# Questions About the New Era

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- What is the responsibility for a company when it comes to a new (or old) drug?
  - Labeling, PMS, how it is used, even if used incorrectly?
  - Risk “Perception” – what is know to science, what is know to user, what is controllable?
- How “safe” must a drug be before it is marketed?
  - Safer than other drugs in the class?
  - How many (what size) studies must be done?