



Pharmacy Industry News

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Recall: Metoprolol ER Tablets by Sandoz

Sandoz is voluntarily extending the September 17, 2008, recall of Metoprolol Succinate Extended Release Tablets 25mg and 50mg, to include all strengths of distributed lots with expiration dates through August 2010. This voluntary action by Sandoz is due to deficiencies in documentation practices and in-process controls for this product. This voluntary recall is being conducted down to the retail level with the knowledge of the FDA. The affected lots were shipped approximately between November 2006 and October 2008. (Sandoz Press Release 11/3/08)

Product Description	Lot #	NDC #
Metoprolol ER Tab 25mg 100's	All Lots with expiry through August 2010	00185-0281-01
Metoprolol ER Tab 25mg 1000's	All Lots with expiry through August 2010	00185-0281-10
Metoprolol ER Tab 50mg 100's	All Lots with expiry through August 2010	00185-0282-01
Metoprolol ER Tab 50mg 1000's	All Lots with expiry through August 2010	00185-0282-10
Metoprolol ER Tab 100mg 100's	All Lots with expiry through August 2010	00185-0283-01
Metoprolol ER Tab 200mg 100's	All Lots with expiry through August 2010	00185-0284-01

Recall: Five generic products by Ethex

Ethex Corporation announced that it has voluntarily recalled to the consumer level specific lots of five generic products. These lots have been recalled as a precaution, due to the possibility that they may contain oversized tablets. Any customer inquiries related to this action should be addressed to Ethex Customer Service at 1-800-748-1472, or fax to ETHEX Customer Service at 314-646-3751 or sent via email to: customer-service@ethex.com. (Ethex Press Release 11/7/08)

Product Description	Lot #	NDC #
Dextroamphetamine 10mg ER Tablets	73934, 75892, 77945, 81137, 86320	58177-0312-04
Morphine 15mg ER Tablets	81175, 82514-16, 89660, 89664, 89667, 90249-51, 91687	58177-0310-04
Morphine 15mg IR Tablets	77852-54, 81746, 82519-20, 84113, 90276-78,	58177-0313-04
Morphine 30mg IR Tablets	75093, 77855-57, 82297, 82521-22, 87239, 88925, 90288-98	58177-0314-04
Propafenone 150mg Tablets	73761, 78184, 79373, 81240-42, 83470, 84357, 90525-26	58177-0331-04
Propafenone 225mg Tablets	71720, 74831, 76014-15, 81243-45, 89731, 90527-29, 90657	58177-0332-04
Propafenone 300mg Tablets	72834, 76016-18, 81246, 89092, 89732, 90530, 90532, 91641-42	58177-0333-04
Isosorbide 30mg ER Tablets	62355, 66423, 68102	58177-0222-04
Isosorbide 60mg ER Tablets	63466, 66034, 67351, 67354	58177-0238-04

Recall: Additional generic products by Ethex

Ethex Corporation announced that it has voluntarily recalled to the retail level specific lots of the generic products listed below. These lots have been recalled as a precaution, due to the possibility that they may contain oversized tablets. Any customer inquiries related to this action should be addressed to Ethex Customer Service at 1-800-748-1472, or fax to ETHEX Customer Service at 314-646-3751 or sent via email to: customer-service@ethex.com.
(Ethex Press Release 11/10/08)

Product Description	Lot #	NDC #
Ethedent 0.5mg Chewable Tablets	82330, 89760, 86325, 96318, 99074,	58177-0433-09, -40
Ethedent 1mg Chewable Tablets	84077, 90107	58177-0434-09, -40
Guaifenesin DM ER Tablets	75845, 84051, 85547	58177-0213-04
Guaifenesin PSE ER 120mg Tablets	84699, 85550-51, 85965	58177-0208-04
NatalCare Gloss Tablets	82384-85, 90534	58177-0418-26
NatalCare PIC Forte Tablets	77215	58177-0258-04
NatalCare Plus Tablets	86283, 86462-63	58177-0225-04
Prenatal MTR/Selenium Tablets	80338	58177-0316-04
Codeine/Guaifenesin 10mg Tablets	85545, 89676, 90060	58177-0223-04
ComBgen Tablets	75954, 90428-29	58177-0440-04
Bupirone 5mg Tablets	75890-91, 79838, 81133, 86318, 89677	58177-0264-04, -08
Bupirone 10mg Tablets	83500-02, 84068-70, 87574, 90080-82	58177-0265-08, -08
Bupirone 15mg Tablets	75889, 79837, 81130-32, 84071-72, 88480	58177-0309-04, -08
Doxazosin 1mg Tablets	74028, 75956-57, 82298-99, 84203, 90464	58177-0266-04, -08
Doxazosin 2mg Tablets	73952-53, 75958-59, 81189-90, 82300, 93496-97, 84314, 89088, 89734	58177-0267-04, -08
Doxazosin 4mg Tablets	73760, 73965, 73968, 75960-61, 76287, 81193-97, 84317, 86504, 86505, 86517, 87007, 87200, 87376-77, 90468-70	58177-0268-04, -08
Doxazosin 8mg Tablets	71709, 73969, 75962-63, 80518, 81201-02, 81630, 82301-02, 84319, 84321, 89738, 98085	58177-0269-04, -08
Hista-Vent DA Tablets	70526, 71639, 72689, 77932, 79676, 81116, 82546, 84056, 87470, 89082, 89956, 90075	58177-0227-04
Hista-Vent PSE Tablets	72859, 74005, 76288, 81117, 84057, 91552-53	58177-0426-04
Hyoscyamine 0.125mg ER Tablets	75077, 77914, 79883, 81300, 82357-58, 88919, 89028, 89648, 90193	58177-0274-04
Hyoscyamine 0.375mg ER Tablets	66002, 67917, 72701, 75074, 76681, 81296-97, 82353, 83918, 87698, 88459, 88911, 89162, 89181, 89645, 89771, 90177-78	58177-0237-04
Hyoscyamine ODT	72837, 75075-76, 77911-12, 82355-56, 84016	58177-0423-04
Hyoscyamine 0.125mg SL Tablets	72821, 74115, 77909, 81298-99, 82354, 83338, 89646, 89772, 90187-88	58177-0255-04
Plavix 8000 Tablets	73764-65, 76042, 76044, 77918, 81289, 82339, 84777, 90163-67, 90901-02, 91648, 92898	58177-0416-04, -08

FDA approves Mylan's generic Keppra

Mylan announced that it received final approval from the FDA for its ANDA for Levetiracetam Tablets 250mg, 500mg and 750mg, the generic version of UCB Pharma's Keppra. The company was the first to file an approval application, meaning that it has the exclusive right to market the tablets for six months. Mylan and UCB had

previously entered an agreement to settle pending litigation relating to levetiracetam. Mylan launched immediately. *(PR Newswire 11/4/08)*

FDA approves Barr subsidiary's generic Camptosar

The FDA has approved a generic version of Pfizer's Camptosar (irinotecan hydrochloride). Pliva, a subsidiary of Barr Pharmaceuticals, will market the drug in vials containing 20mg/mL, 40mg/2mL and 100mg/5mL. *(FDA Week 11/4/08)*

FDA approves Strides' generic Aredia

The FDA has approved the application of Indian drug maker Strides Arcolab for injected pamidronate disodium in 3mg/mL and 9mg/mL single-use vials, the generic version of Novartis's Aredia. *(Drug Store News 11/6/08)*

FDA approves generic version of Imitrex Injection

Par and Sandoz announced that they received final approval from the FDA for its ANDA for sumatriptan succinate injection, the generic version of Imitrex Injection. Both Par and Sandoz will market the kit and refill for sumatriptan. Imitrex Injection had U.S. sales of approximately \$220 million for the year ending March, 31st, 2008, according to IMS sales data. *(Press Release 11/6/08)*

Barr and Biovail sued in separate patent suits

Cephalon and Cima are suing Barr in for infringing on patents covering Fentora (fentanyl citrate), according to court documents. Both patents expire March 26, 2019. Separately, Abbott Laboratories and Laboratoires Fournier have filed suit against Biovail Laboratories for infringing on patents covering the 48mg and 145mg versions of TriCor (fenofibrate), which expire in January 2018. *(Drug Industry Daily 11/6/08)*

Daiichi completes Ranbaxy acquisition

Japan's Daiichi Sankyo has completed its \$4 billion acquisition of Ranbaxy Laboratories, India's largest pharmaceutical company, according to the companies. Daiichi Sankyo agreed to buy a controlling stake in Ranbaxy in June, and the transfer of 63.92 percent of Ranbaxy's equity shares to Daiichi was completed November 7th, the companies said. Daiichi paid \$15.42 per share, according to a Ranbaxy spokesman. *(Associated Press 11/7/08)*

Takeda wins appeal against Teva over Prevacid

Takeda Pharmaceutical won a U.S. appeals court ruling that prevents Teva Pharmaceutical from selling a generic version of Prevacid (lansoprazole) until 2009. The U.S. Court of Appeals for the Federal Circuit, without issuing an opinion, upheld a judge's decision that a patent on the medicine is both valid and enforceable. *(Bloomberg 11/10/08)*

Democratic platform may provide biogeneric pathway

Obama's health care plan and the Democratic Party's platform both promise a pathway for biogenerics. The Biotechnology Industry Organization was looking to push through a bill this year, with concern that a Democratic Congress and White House would be more friendly to generics. *(Inside Health Policy 11/5/08)*

Generic drugs lower Medicare costs

According to PharmaTimes, generic drugs helped lower Medicare costs and accounted for 64% of all prescriptions written under the the prescription drug benefit. The Congressional Budget Office had predicted that by 2008 Medicare annual costs would reach \$74 billion, however, in 2008 the actual figure is close to \$50 billion. In addition, Medicare's basic monthly drug coverage premium for 2008 was \$26.70, almost a third less than originally predicted. *(Pharmaceutical Business Review 11/5/08)*

U.S. officials and drug industry anticipate new FDA leadership

Drug companies, patient advocates and U.S. officials are awaiting President-elect Barack Obama's choice for the next leader of the FDA, which has been criticized for its lapses in product-safety regulation. The new administration should restore the FDA's independence, a former agency official said. *(Reuters 11/6/08)*

Congress may create biogeneric pathway in 2009, according to Medco CEO

Legislation aimed at creating an approval pathway for follow-on biologics could be passed next year as Democrats dominate Congress, said Dave Snow, CEO of Medco Health Solutions. Such a law would benefit

Medco and other pharmacy-benefits managers, which gain significant profit from generic drugs. (*Wall Street Journal 11/6/08*)

Drug companies support Woodcock as FDA Commissioner

Pharmaceutical companies are calling on President-elect Barack Obama to appoint Janet Woodcock, a senior FDA official, as the next commissioner of the agency, according to industry sources. An FDA spokeswoman stated Woodcock declined to comment, while the Pharmaceutical Research and Manufacturers of America chose not to talk about possible candidates. (*Bloomberg 11/7/08*)

Generic Drugs Office states response requirement to Citizen Petitions a burden

FDA Office of Generic Drugs Director Gary Buehler stated the FDA is struggling with the "huge amount of work" that has resulted from a requirement in the FDA Amendments Act that FDA respond to new citizen petitions within 180 days. Petitions submitted before the 180-day review requirement took effect are lingering, he said. Buehler spoke at the Generic Pharmaceutical Association's Technical Conference October 29th in Bethesda, MD. (*FDA Week 11/7/08*)