



Walmart's \$4 Drugs Coming From Indian Company Whose Products Have Been Banned In US and Canada

WakeupWalmart.com supports the use of generic prescription drugs as a safe alternative to expensive, name-brand medications. Walmart's use of a corporate bad actor to cut costs, however, deserves significant scrutiny.

Walmart is heavily promoting a program of 30-day supplies of generic drugs for \$4, pointing to the program as an indicator of the company's leadership on making healthcare more affordable. To profit on \$4 dollar prescriptions, Walmart is importing drugs from foreign countries, including India.¹ Walmart competitor Costco went a different direction in late 2006, when it ended its \$4 dollar prescription drug plan because it was losing money selling prescription drugs at such a low price.² Costco switched to selling 100 pills for \$10.

One of Walmart's Indian drug suppliers, Ranbaxy Laboratories, LTD, has been repeatedly investigated by the Food and Drug Administration and the Department of Justice for "inadequate" safeguards against contamination, falsification of records and submitting false information to the FDA.³ Eight months before the FDA inspected Ranbaxy's Paonta Sahib plant and found significant violations, Walmart awarded the company a "Supplier Award" for improving shipping times and performance.⁴

In 2008, the FDA banned importation of drugs manufactured at two of Ranbaxy's plants,⁵ and in 2009, the FDA halted review of applications to import drugs manufactured at the Paonta Sahib plant.⁶ Soon thereafter, Canada followed suit and banned importation of drugs manufactured at that facility.⁷

Yet Walmart still imports generic drugs made by Ranbaxy at its other Indian facilities.

2009 Violations

In February 2009, the Food and Drug Administration announced it had halted review of importation applications for generic drugs manufactured at Ranbaxy's Paonta Sahib plant owned by Ranbaxy Laboratories, LTD, an Indian generic drug manufacturer, "due to evidence of falsified data."⁸ According to the FDA press release, Ranbaxy "falsified data and test results in approved and pending drug applications."⁹ In the warning letter sent to Ranbaxy, the FDA cited

¹ RanbaxyUSA.com, accessed 5/26/09

² [Dow Jones Newswires](#), 12/25/06

³ [FDA press release](#), 2/25/09

⁴ [Ranbaxy Laboratories press release](#) 6/21/05

⁵ [Food and Drug Administration press release](#), 9/16/08

⁶ [FDA press release](#), 2/25/09

⁷ [World Markets Research Centre](#), 3/3/09

⁸ [FDA press release](#), 2/25/09

⁹ [FDA press release](#), 2/25/09



seven examples of false statements made by Ranbaxy to the FDA.¹⁰ According to FDA records, this was the third time Ranbaxy's Paonta Sahib facility had run afoul of federal Food and Drug laws.¹¹

The FDA did include a caveat in its release, stating that the agency "has no evidence that these drugs do not meet their quality specifications and has not identified any health risks associated with currently marketed Ranbaxy products."¹²

A week after the FDA announced it was halting review of Paonta Sahib applications, Canada announced it was "quarantining" all drugs produced at the Paonta Sahib plant.¹³

2008 Violations

Previously, in September 2008, the FDA issued warning letters to Ranbaxy regarding "significant deviations" from FDA standards for the manufacture of drugs sold in the United States. According to an FDA press release, the agency also banned the importation of any Ranbaxy drugs produced at the company's Dewas and Paonta Sahib plants.

According to the release, the Dewas plant's cross-contamination prevention program was "insufficient." These programs are designed to prevent cross-contamination between different types of drugs. The plant also used "inadequate" sterilization procedures and performed "inadequate failure investigations." According to the FDA release, failure investigations are performed "to address any manufacturing control or product rejection to determine the root cause and prevent recurrence." The Paonta Sahib plant had "inaccurate" records regarding cleaning and maintaining of its equipment and "incomplete" records.¹⁴

Deborah Autor, director of the Office of Compliance at the FDA's Center for Drug Evaluation and Research, announced that the "severe violations" had led the FDA to ban importation of drugs from these plants and to deny any new drug import applications for drugs manufactured at these plants.¹⁵

Before the warning letters were sent and the sanctions put in place, Ranbaxy had the opportunity to rectify the problems at the Dewas and Paonta Sahib plants; however, the company's "response failed to adequately address multiple, serious deficiencies."¹⁶

2006 Violations

The FDA had issued a previous warning letter in June 2006 to Ranbaxy regarding "significant deficiencies" in the Paonta Sahib plant's "stability testing program."¹⁷ According to Ranbaxy

¹⁰ [FDA Warning Letter regarding Paonta Sahib plant, 2/25/09](#)

¹¹ [FDA Warning Letter regarding Paonta Sahib plant, 9/16/08](#)

¹² [FDA press release, 2/25/09](#)

¹³ [World Markets Research Centre, 3/3/09](#)

¹⁴ [Food and Drug Administration press release, 9/16/08](#)

¹⁵ [Food and Drug Administration press release, 9/16/08](#)

¹⁶ [FDA Warning Letter regarding Dewas plant, 9/16/08](#)

¹⁷ [FDA Warning Letter regarding Paonta Sahib plant, 6/15/06](#)



documents produced under subpoena, Ranbaxy was first notified of the violations by the FDA on February 25, 2006.¹⁸

During the FDA's inspection of the Paonta Sahib plant, the agency found fourteen instances where equipment cleaning records were signed by employees who "were not shown as present by security log records."¹⁹

Department of Justice Involvement

In July 2008, the Department of Justice filed a motion to enforce subpoenas issued to Ranbaxy in federal court. The motion stated Ranbaxy's 2006 violations "have resulted and continue to result in the introduction of adulterated and misbranded products into interstate commerce with the intent to defraud or mislead."²⁰

The motion continued:

Allegations from reliable sources and supporting documents indicate a pattern of systemic fraudulent conduct, including submissions by Ranbaxy to the FDA that contain false and fabricated information about stability and bioequivalence, failure to timely report the distribution of drugs that were out-of-specification ("OOS"), and attempts to conceal violations of current Good Manufacturing Practices ("cGMP") regulations from the FDA.

Evidence suggests that Ranbaxy uses API [Active Pharmaceutical Ingredients] from unapproved sources, blends unapproved APIs with approved APIs, and uses less API in its drug than had been approved by the FDA. Any of these conditions would cause a drug to be subpotent, superpotent, or adulterated.²¹

Congressional Investigation

According to a press release issued by the U.S. House of Representatives Committee on Energy and Commerce, the committee launched an investigation into "whether the Food and Drug Administration (FDA) knowingly allowed drugs suspected of being fraudulently approved and manufactured in gross violation of Good Manufacturing Practices (GMP) to continue being sold by Ranbaxy, Inc., in the United States" in July 2008, before the import ban.²² According to a September 2008 committee press release, in response to the FDA warning letters, the FDA possessed "credible information" that Ranbaxy "had engaged in a pattern of fraudulent behavior regarding its generic drug applications and records pertaining to good manufacturing practices" dating back to 2005. The committee found that the FDA had only inspected 17 percent of Ranbaxy's approved import applications.²³

Changes At The Company

¹⁸ [Ranbaxy Laboratories meeting summary](#), 11/29/06

¹⁹ [FDA Warning Letter regarding Paonta Sahib plant](#), 9/16/08

²⁰ [United States of America vs. Ranbaxy, Inc., Case #8:08-cv-01764-PJM, complaint filed 7/3/08](#)

²¹ [United States of America vs. Ranbaxy, Inc., Case #8:08-cv-01764-PJM, complaint filed 7/3/08](#)

²² [House Energy and Commerce Committee press release](#), 7/22/08

²³ [House Energy and Commerce Committee press release](#), 9/16/08



At the end of May 2009, Ranbaxy's chairman, Malvinder Singh, resigned under pressure from its Japanese parent company.²⁴ And the company has submitted another corrective action plan to the Food and Drug Administration to attempt to have the import ban lifted and have the company's applications to import new drugs manufactured at those plants considered.²⁵

Drugs Imported Into The U.S. From Ranbaxy Plants Where Violations Occurred

According to the FDA, the following drugs are manufactured at the Dewas and Paonta Sahib facilities owned by Ranbaxy Laboratories, Ltd and are affected by the import alert.²⁶

These drugs are used to treat bacterial infections, kidney or bladder infections, ulcers, high cholesterol levels, high blood pressure, seizures, acne, allergies, depression, high blood sugar (diabetes), ulcers and acid reflux, cold sores and HIV.²⁷

Drug:	Use:
Acyclovir	prevents herpes simplex virus-the virus that causes chickenpox, cold sores, and genital herpes-from reproducing.
Amoxicillin; Amoxicillin and Clavulanate Potassium	a penicillin-type antibiotic used to treat a wide variety of bacterial infections. It works by stopping the growth of bacteria.
Carbidopa and Levodopa	is used to treat the symptoms of Parkinson's disease or Parkinson-like symptoms.
Cefaclor	is a cephalosporin-type antibiotic used to treat a wide variety of bacterial infections (e.g., middle ear, skin, urine and respiratory tract infections).
Cefadroxil	is a cephalosporin-type antibiotic used to treat a wide variety of bacterial infections (e.g., strep throat, skin and urinary tract infections).
Cefpodoxime Proxetil	is used to treat a wide variety of bacterial infections.
Cefprozil	is used to treat a wide variety of bacterial infections.
Cefuroxime Axetil	is used to treat a wide variety of bacterial infections.
Cephalexin	is a cephalosporin-type antibiotic used to treat a wide variety of bacterial infections (e.g., skin, bone and genitourinary tract infections).
Ciprofloxacin HCl	is used to treat kidney or bladder (urinary tract) infections.
Clarithromycin	is used to treat a wide variety of bacterial infections. This medication can also be used in combination with anti-ulcer medications to treat certain types of stomach ulcers. It may also be used to prevent certain bacterial infections.
Fenofibrate	is used along with diet and exercise to help control levels of blood fats. It can help lower "bad" cholesterol (LDL) and

²⁴ [BusinessWeek](#), 5/27/09

²⁵ [The Economic Times](#), 5/29/09

²⁶ <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/ucm118441.htm>, accessed 5/21/09

²⁷ [WebMD.com](#), accessed 5/21/09



	triglycerides and raise "good" cholesterol (HDL). In general, this drug is used after your blood fat levels have not been fully controlled by non-drug treatments (e.g., diet changes, exercise, decreasing alcohol intake, weight loss if overweight, and controlling blood sugar if diabetic).
Fluconazole	is an azole antifungal medication used to prevent and treat a variety of fungal and yeast infections.
Fosinopril Sodium	belongs to a group of medications called ACE inhibitors. It is used to treat high blood pressure (hypertension). It works by relaxing blood vessels, causing them to widen.
Fosinopril Sodium and Hydrochlorothiazide	is used to treat high blood pressure. Lowering high blood pressure helps prevent strokes, heart attacks, and kidney problems. Hydrochlorothiazide is a "water pill" (diuretic) that causes your body to get rid of extra salt and water.
Gabapentin	is used with other medications to help control seizures in adults and children (3 years of age and older). It is also used to relieve nerve pain associated with shingles (herpes zoster) infection in adults. Gabapentin may also be used to treat other nerve pain conditions (e.g., diabetic neuropathy, peripheral neuropathy, trigeminal neuralgia).
Glimepiride	is an anti-diabetic drug (sulfonylurea-type) used along with a proper diet and exercise program to control high blood sugar. It is used in patients with type 2 diabetes (non-insulin-dependent diabetes).
Isotretinoin	is used to treat severe cystic acne (also known as nodular acne) that has not responded to other treatment (e.g., benzoyl peroxide or clindamycin applied to the skin or tetracycline or minocycline taken by mouth).
Loratadine (OTC)	is an antihistamine that treats symptoms such as itching, runny nose, watery eyes, and sneezing from "hay fever" and other allergies. It is also used to relieve itching from hives.
Metformin HCl	is used with a proper diet and exercise program to control high blood sugar in people with type 2 diabetes (non-insulin-dependent diabetes).
Nefazodone HCl	is used to treat depression. Nefazodone works by helping to restore the balance of certain natural chemicals (neurotransmitters such as serotonin, norepinephrine) in the brain.
Nitrofurantoin; Nitrofurantoin and Macrocrystalline	is used to treat or prevent certain urinary tract infections.
Ofloxacin	is used to treat a variety of bacterial infections.
Pravastatin Sodium	is an enzyme blocker (HMG-CoA reductase inhibitor), also known as a "statin". It is used in adults and children (8 years of age and older), along with a proper diet, to help lower cholesterol and fats (triglycerides) in the blood.



Ranitidine	is used to treat ulcers of the stomach and intestines and prevent them from returning after treatment. This medication is also used to treat and prevent certain stomach and throat (esophagus) problems caused by too much stomach acid (e.g., Zollinger-Ellison syndrome, erosive esophagitis) or a backward flow of stomach acid into the esophagus (gastroesophageal reflux disease-GERD).
Terazosin HCl	is used alone or in combination with other drugs to treat high blood pressure. It works by relaxing blood vessels so blood can flow more easily.
Valacyclovir HCl	is used in children to treat cold sores (herpes labialis) and chickenpox (varicella zoster). It is used in adults to treat cold sores and shingles (herpes zoster). Valacyclovir does not cure these diseases, but it may decrease pain and help sores heal faster. Valacyclovir is also used to treat people with genital herpes who are currently having an outbreak. It can also be used to prevent an outbreak (suppressive therapy).
Zidovudine	is used in combination with other medications to help control your HIV infection, thereby improving your quality of life. It also lowers your risk of getting HIV disease complications (e.g., new infections, cancer).
[All usage information from WebMD.com, accessed 5/21/09]	