FDA cracks down on unapproved narcotic painkillers

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(AP) -- The government ordered 14 unapproved narcotic painkillers off the market Tuesday, prescription versions of potent morphine, hydromorphone and oxycodone. The Food and Drug Administration told nine manufacturers to quit distributing the drugs within 90 days - but insisted there are plenty of legal versions of the painkillers being sold for patients who need relief.

"There will be no shortage for consumers," said Deborah Autor, director of FDA's drug compliance office.

The move is part of the FDA's years-long attempt to weed out thousands of prescription drugs that sell despite never being formally approved by the health regulatory agency. Many entered the market decades ago, before federal law required such approval. The FDA estimates that unapproved drugs account for 2 percent of all prescriptions filled.

Tuesday, the FDA targeted unapproved versions of high-concentrate liquid morphine sulfate and unapproved immediate-release tablets containing morphine sulfate, hydromorphone and oxycodone. Most are generic.

To help consumers tell if they have an approved or unapproved version, the FDA posted both lists on its Web site: http://www.fda.gov/cder/drug/unapproved-drugs/narcoticsQA.htm .

Manufacturers receiving warning letters Tuesday are: Boehringer

Ingelheim Roxane Inc. of Columbus, Ohio; Cody Laboratories Inc. of Cody, Wyo.; Glenmark Pharmaceuticals Inc. of Mahwah, N.J.; Lannett Co. Inc. of Philadelphia; Lehigh Valley Technologies Inc. of Allentown, Pa.; Mallinckrodt Inc. Pharmaceuticals Group of St. Louis; Physicians Total Care inc. of Tulsa; Roxane Laboratories Inc. of Columbus, Ohio; and Xanodyne Pharmaceutical Inc. of Newport, Ky.

The largest, Boehringer, didn't immediately return a call seeking comment.

Even FDA-approved versions of these painkillers pose a risk of serious side effects, but the unapproved products add an extra problem: Regulators haven't checked that those versions work as well and are as pure as their approved competitors.

Companies that don't heed the FDA's deadline could face big penalties: The government once seized $24 million worth of unapproved drugs from a company that ignored a stop-selling order, Autor noted.