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## **FDA News**

### **FOR IMMEDIATE RELEASE**

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### **FDA Advances Effort Against Marketed Unapproved Drugs *FDA Orders Unapproved Quinine Drugs from the Market and Cautions Consumers About "Off-Label" Use of Quinine to Treat Leg Cramps***

The Food and Drug Administration (FDA) today ordered firms to stop marketing unapproved drug products containing quinine, a drug used to treat malaria, citing serious safety concerns, including deaths, associated with quinine products. There are multiple unapproved products containing quinine currently marketed. However, there is only one quinine product approved by the FDA.

As part of its action, FDA is also cautioning consumers about off-label use of quinine to treat leg cramps. Quinine is approved for treatment of malaria, but is also commonly prescribed to treat leg cramps and similar conditions. Because malaria is life-threatening, the risks associated with quinine use are justified for that condition. But because of the drug's risks, FDA believes it should not be used to prevent or treat leg cramps.

The action posted in a Federal Register notice is part of FDA's continued efforts against unapproved drug products.

"Providing the American public with safe and effective medical products is our core mission," said Dr. Andrew von Eschenbach, Acting Commissioner of Food and Drugs. "The presence of unapproved drugs on the U.S. market is in stark contrast to our current approach to drug safety because those drugs may not meet modern standards for safety, effectiveness, quality, and labeling. As part of our drug safety efforts, we are committed to ensuring all marketed drugs have required FDA approval."

One quinine drug product, Mutual Pharmaceutical Company, Inc.'s Qualaquin, is FDA-approved to treat certain types of malaria without complications. Unlike the approved product, many unapproved quinine drug products are marketed without labeling cautioning against use of the product for treatment of leg cramps. The FDA-approved labeling for the product provides extensive warnings regarding serious adverse events associated with use of quinine, potentially serious interactions with other drugs, and conditions under which quinine should not be used. Quinine is a drug with a narrow margin between an effective dose and a toxic dose. The dosing for the approved drug is supported by data to maximize the safety and efficacy of the product. The dosing for the unapproved drugs has not been reviewed and approved by FDA.

Since 1969, FDA has received 665 reports of adverse events with serious outcomes associated with quinine use, including 93 deaths. Quinine drugs are associated with serious side effects, such as cardiac arrhythmias, thrombocytopenia (a decrease in blood platelets that can cause hemorrhage or clotting problems), and severe hypersensitivity reactions.

There is also the potential for serious interactions between quinine drugs and other drugs, and there are conditions under which quinine should not be used.

Under today's action, previously manufactured unapproved products may still be found on pharmacy shelves for a short period of time, but manufacturing of new product must cease in 60 days. The agency urges consumers who are using quinine products and have questions or concerns to contact their health care provider.

"This summer, when the agency began its aggressive efforts to remove unapproved drugs from the market, we vowed to target the products with the most serious public health risks," said Dr. Steven Galson, Director of the FDA's Center for Drug Evaluation and Research (CDER). "We believe unapproved quinine products represent a serious health risk because of the widespread use of this product for treating leg cramps. Quinine needs to be dosed carefully, and FDA-approved labeling reflects the fact that the risks associated with the use of this drug for treatment of leg cramps outweigh the benefits."

### **Update on FDA's Effort Against Marketed Unapproved Drugs**

In June, 2006, FDA issued a new guidance, "Marketed Unapproved Drugs – Compliance Policy Guide," which makes clear that firms illegally marketing drugs without FDA approval need to submit applications showing that their products are safe and effective before continuing to market those products. FDA's actions against unapproved drugs are part of the agency's broader initiative, launched last year, to ensure that consumers and the health care community are provided with established and emerging drug safety information so that they can make the best possible medical decisions about the safe and effective use of drugs. Since the FDA announced this initiative, the agency has issued warning letters to several companies that are manufacturing unapproved drugs and federal courts have entered permanent injunctions against two others. FDA expects to further accelerate its enforcement efforts against marketed unapproved drugs in 2007.

The agency also announced that Acting Commissioner Von Eschenbach, will speak at the agency's January 9, 2007, workshop on marketed unapproved drugs. The workshop will provide clarification and direction to businesses on how to seek approval to legally market drugs through the new drug application and abbreviated new drug application processes, as well as how to legally market drugs through compliance with over-the-counter drug monographs. Due to the very large number of registrants, the agency has closed registration for the workshop and designated a new venue. To accommodate the attendees, the workshop will now be held at the Universities at Shady Grove, Conference Center Auditorium, Rockville, Maryland.

"We are encouraged by the tremendous response we have received for this workshop," said Deborah M. Autor, Esq., Director of the CDER Office of Compliance. "This is a clear indication that manufacturers are heeding our warning to bring unapproved drugs into compliance or risk having them removed from the market."

For additional information, please see FDA's Unapproved Drugs Web Page, located at [http://www.fda.gov/cder/drug/unapproved\\_drugs](http://www.fda.gov/cder/drug/unapproved_drugs).

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