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FDA NEWS RELEASE

FOR IMMEDIATE RELEASE

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FDA Requests Boxed Warnings on Fluoroquinolone Antimicrobial Drugs Seeks to Strengthen Warnings Concerning Increased Risk of Tendinitis and Tendon Rupture

The U.S. Food and Drug Administration (FDA) has notified manufacturers of fluoroquinolone antimicrobial drugs that a Boxed Warning in the product labeling concerning the increased risk of tendinitis and tendon rupture is necessary. Through its new authority under the Food and Drug Administration Amendments Act of 2007 (FDAAA), the agency also determined that it is necessary for manufacturers of the drugs to provide a Medication Guide to patients about possible side effects.

The FDA has notified the manufacturers of these drugs that a Risk Evaluation and Mitigation Strategy (REMS) is necessary to ensure that the benefits of the drug outweigh the risks. The Medication Guide will be considered to be an element of the REMS. The new Boxed Warning and Medication Guide would strengthen warning information already included in product labeling for the fluoroquinolone class of systemic antimicrobial drugs.

Fluoroquinolones are drugs approved for the treatment or prevention of certain bacterial infections. Like other antibacterial drugs, fluoroquinolones do not treat viral infections such as colds or flu.

"Fluoroquinolones are effective in treating certain bacterial infections, but health care professionals and patients need to be aware of the increased risk associated with the use of these drugs of developing tendinitis and tendon rupture, particularly for certain patient populations," said Edward Cox, M.D., director, Office of Antimicrobial Products, Center for Drug Evaluation and Research. "The FDA believes it is important to highlight and strengthen information regarding possible side effects of fluoroquinolones because it may affect decisions about the relative risks and benefits associated with these products."

The FDA has conducted a new analysis of the available literature and post-marketing adverse event reports. This new analysis reconfirms that use of fluoroquinolones is associated with an increased risk of tendon rupture. It also demonstrates that despite the current warning of tendon rupture in the labeling for the fluoroquinolones, large numbers of tendon-related adverse events continue to be reported. The FDA considers this new analysis to be "new safety information" as defined in FDAAA.

The FDA also issued Information for Health Care Professionals today to alert health care professionals to the increased risk of tendinitis and tendon rupture in patients taking these drugs and to highlight new information concerning who may be at higher risk for this side effect.

The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is further increased in people older than 60, in those taking corticosteroid drugs, and in kidney, heart, and lung transplant recipients. Patients experiencing pain, swelling, inflammation of a tendon or tendon rupture should be advised to stop taking their fluoroquinolone medication and to contact their health care professional promptly about changing their antimicrobial therapy. Patients should also avoid exercise and using the affected area at the first sign of tendon pain, swelling, or inflammation.

Manufacturers are being notified of the need to change labeling so that all of the drugs in the class carry uniform updated warning language. These warnings would apply to fluoroquinolones for systemic use (e.g., pills, tablets, capsules and injectable formulations). The warnings would not apply to fluoroquinolones for topical ophthalmic or otic use (e.g., eye and ear drops).

Fluoroquinolone manufacturers are required to submit the safety labeling changes, including the strengthened warnings and the Medication Guide, to the FDA within 30 days, or to provide a reason why they do not believe such labeling changes are necessary. If they do not submit new language, or the FDA disagrees with the new language the company proposes, FDAAA provides strict timelines for resolving the labeling changes and allows the agency to issue an order directing the labeling change as deemed appropriate to address the new safety information. In addition, in accordance with FDAAA, sponsors will be required to assess whether their REMS are achieving the goal of informing patients of the risk of tendon-rupture. These assessments may include a survey of patients' and prescribers' understanding of the risks of tendon-rupture and whether the Medication Guide is being distributed and dispensed with the drug.

Health care professionals should consider the potential benefits and risks for each patient. While most patients tolerate these medicines well, occasionally some will develop other serious adverse reactions that may include convulsions, hallucinations, depression, abnormalities in heart rhythm, or severe diarrhea.

The medications involved in this action are: Cipro and generic ciprofloxacin, Cipro XR and Proquin XR (ciprofloxacin extended

release), Factive (gemifloxacin), Levaquin (levofloxacin), Avelox (moxifloxacin), Noroxin (norfloxacin), and Floxin and generic ofloxacin.

Information for Healthcare Professionals on Fluoroquinolone Antimicrobial Drugs: <http://www.fda.gov/cder/drug/InfoSheets/HCP/fluoroquinolonesHCP.htm>

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