The US Food and Drug Administration has told manufacturers of fluoroquinolones to warn doctors and patients of the raised risk of tendinitis and tendon rupture. The “black box” warning, the most stringent, must be added to drug labels and prescribing information, and manufacturers must also develop a treatment guide for patients.

These measures, the FDA said on 8 July, would strengthen the existing warnings in the prescribing information for fluoroquinolones. The warnings apply to tablets, capsules, and injectable formulations for systemic use but not to ophthalmic or otic formulations.

Public Citizen, a non-profit consumer rights organisation, said that the FDA had accomplished “two of the three steps Public Citizen has urged the agency to do for nearly two years.” The third step, which FDA did not take, was to send a warning letter to doctors “clearly describing possible adverse reactions, such as tendon pain, so that patients can be switched to alternative treatments before tendons rupture.”

Public Citizen, together with the Illinois attorney general, petitioned the FDA in August 2006 to strongly warn the public about the risk of tendon rupture. When the FDA did not act it sued the agency in January to compel it to act.

Public Citizen says that more than 100 cases of tendon rupture could have been avoided if the FDA had acted more quickly. It said, “From November 1997 through December 2007, there have been 407 reported cases of tendon rupture and 341 cases of tendinitis in patients using fluoroquinolone antibiotics. Because only a small fraction of cases are typically reported to the FDA, the actual number of ruptures and other tendon injuries attributable to the antibiotic is much higher.”

The most common rupture was of the Achilles tendon.

The drugs affected by the new warning include ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin, norfloxacin, and ofloxacin.

The FDA said the risk of tendinitis and tendon rupture was higher in people aged over 60, patients who had received kidney, heart, or lung transplants, and people taking steroid treatment. It said that doctors should tell patients to stop taking fluoroquinolones at the first sign of tendon pain, swelling, or inflammation, to avoid exercise and use of the affected area, and to contact a doctor promptly about changing to a non-fluoroquinolone antibiotic.

Although most patients do not have problems, the FDA told doctors to consider the benefits and risks for each patient before prescribing a fluoroquinolone and to use them only for treating or preventing infections caused by bacteria. It also noted that patients may develop other serious adverse effects, including convulsions, hallucinations, depression, prolonged QTc (corrected QT interval) and torsades de pointes, and Clostridium difficile associated diarrhoea.