

FDA toughens warnings on over-the-counter painkillers

April 29 2009, By Val Brickates Kennedy

The Food and Drug Administration said Tuesday that it is asking drugmakers to more prominently display safety warnings on the labels of some of the most widely used over-the-counter pain and fever remedies.

FDA officials said they are requiring new labeling on products containing acetaminophen, which is marketed under brand names such as Tylenol.

The labeling would also cover products containing non-steroidal anti-inflammatory drugs, or NSAIDs, which include drugs such as ibuprofen, [aspirin](#) and [naproxen](#). The medications are marketed under brand names such as Advil, Motrin and Aleve.

The products are marketed by a number of drugmakers, including Johnson & Johnson, Bayer AG and Wyeth.

More specifically, the FDA said that all products containing acetaminophen must have a prominent warning on both the inner container and the outer box advising the product can cause severe liver damage when used in amounts beyond the maximum dose.

Liver damage can also be sustained if the user drinks more than three alcoholic beverages a day while using the product or already has liver disease.

The acetaminophen label will also advise users that combining the drug

with the blood thinner warfarin can cause serious bleeding problems. Likewise, users should avoid taking acetaminophen with other products that contain the drug, such as cold and sinus remedies.

As for NSAIDs such as ibuprofen, the new label will warn users the drugs can cause stomach bleeding in people who are also taking steroids or blood thinners, take more of the product than is directed or who have existing stomach problems.

NSAID users will also be cautioned not to drink three or more alcoholic drinks a day while taking the product. People over age 60 should also watch for signs of stomach bleeding when taking the drug.

The NSAID label will also list symptoms of stomach bleeding.

The [FDA](#) said drugmakers will have a year to comply with the labeling request.

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Citation: FDA toughens warnings on over-the-counter painkillers (2009, April 29) retrieved 8 April 2024 from <https://medicalxpress.com/news/2009-04-fda-toughens-over-the-counter-painkillers.html>

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