

FDA seeks faster warning updates for generic drugs

November 8 2013

The Food and Drug Administration is seeking a rule change to allow generic drugmakers to quickly update their warning labels with new safety information for doctors and patients.

Current regulations require generic drugs to bear the same labels as their branded counterparts. That policy has left generic companies with little control over their drug labels, and also shielded them from legal liability in court.

In 2011, the Supreme Court ruled that generic drugmakers cannot be sued for failing to warn consumers about possible side effects of their products if they use the exact same warnings as the original medicines.

Under today's proposal, generic drugmakers would have the same power as brand-name drug makers to update their drugs with new information.

Regulators will take comments on the proposal for 60 days.

© 2013 The Associated Press. All rights reserved.

Citation: FDA seeks faster warning updates for generic drugs (2013, November 8) retrieved 17 April 2024 from https://medicalxpress.com/news/2013-11-fda-faster-drugs.html

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.