

[Print this page](#)[Close this window](#)

## FDA staff urges psych warning for flu drug labels

URL of this page: [http://www.nlm.nih.gov/medlineplus/news/fullstory\\_57973.html](http://www.nlm.nih.gov/medlineplus/news/fullstory_57973.html) (\*this news item will not be available after 12/23/2007)



Friday, November 23, 2007

WASHINGTON (Reuters) - U.S. Food and Drug Administration staff are recommending new warnings about psychiatric events observed in patients on Roche Holding AG's Tamiflu and GlaxoSmithKline Plc's Relenza, according to documents posted on Friday.

An FDA advisory panel will discuss the recommendations for these influenza drugs at a meeting on the drugs' safety next week. The FDA held a similar meeting two years ago on Tamiflu, after reports of deaths of children in Japan linked to abnormal psychiatric behavior.

Experts two years ago were unable to find a connection between the drug and the deaths.

In documents prepared for the meeting next week and posted on the FDA Web site, FDA staff recommend that Tamiflu's label be changed to note "some cases in Japanese adult and pediatric patients resulted in a fatal outcome."

The FDA staff also reviewed Relenza, a drug in the same class as Tamiflu, recommending its label be changed to note "reports of hallucinations, delirium and abnormal behavior" observed in some patients taking the drug.

Copyright © 2007 Reuters Limited. All rights reserved. Republication or redistribution of Reuters content, including by framing or similar means, is expressly prohibited without the prior written consent of Reuters. Reuters shall not be liable for any errors or delays in the content, or for any actions taken in reliance thereon. Reuters and the Reuters sphere logo are registered trademarks and trademarks of the Reuters group of companies around the world.

---

### Related MedlinePlus Pages:

- Drug Safety - <http://www.nlm.nih.gov/medlineplus/drugsafety.html>
- Flu - <http://www.nlm.nih.gov/medlineplus/flu.html>

Date last updated: 26 November 2007