FDA investigates deaths of patients on antipsychotic drug

June 19 2013

Following the deaths of two patients three to four days after receiving a dose of Zyprexa Relprevv (olanzapine pamoate) via intramuscular injection, the U.S. Food and Drug Administration is conducting an investigation into the possible cause.

(HealthDay)—Following the deaths of two patients three to four days after receiving a dose of Zyprexa Relprevv (olanzapine pamoate) via intramuscular injection, the U.S. Food and Drug Administration is conducting an investigation into the possible cause.

The patients were well outside the three-hour window of monitoring required by the antipsychotic drug's Risk Evaluation and Mitigation Strategy (REMS), but were found to have very high blood levels of olanzapine after death.

In addition to the three-hour monitoring period, REMS protocol requires patients to receive injections only at REMS-certified facilities and to be accompanied home after the monitoring period. The drug's label warns

against possible post-injection delirium sedation syndrome, in which the agent enters the blood too quickly and causes heavy sedation (possibly coma) and/or delirium.

According to the agency, "FDA is providing this information to health care professionals while it continues its investigation. If therapy with Zyprexa Relprevv is started or continued in patients, health care professionals should follow the REMS requirements and drug label recommendations. Patients and caregivers should talk to their health care professional(s) about any questions or concerns."

More information: More Information