U.S. health regulators have warned Pfizer Inc over a series of failures that led to the overdosing of at least 13 children in a clinical trial of its antipsychotic drug Geodon, according to a letter made public on Tuesday.

The FDA, in an April 9 warning letter to the world's largest drugmaker, said Pfizer "failed to ensure proper monitoring" of the trial in which several children given overdoses experienced tremors, restless legs and other complications.

The company is seeking to market the drug to children with bipolar disorder and has received cautious support from a U.S. advisory panel. While the study in question ended in 2007, the FDA is concerned Pfizer has not done enough to ensure the problem does not happen again.

Its concerns come amid continuous unease over the use of powerful drugs to treat depression, schizophrenia, bipolar disorder and other mental illness in youth. Many experts are concerned that such medications -- widely used to treat adults -- may not work the same in children and teenagers whose brains are still developing.

Geodon, first approved in 2001 for adults with schizophrenia, is already cleared for adults with bipolar disorder. Companies which study approved drugs in children can not only seek approval of pediatric use of their therapies, but also an added 6 months of patent protection under U.S. law.

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