Questions remain about safety of Parkinson disease psychosis drug

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(HealthDay)—There are many unanswered questions about the safety

and effectiveness of a drug used to combat hallucinations and delusions in Parkinson disease patients, says a report from a drug safety group. The nonprofit Institute for Safe Medication Practices (ISMP) called for Nuplazid to have stronger warnings on its label for patients and their families, *CNN* reported.

The U.S. Food and Drug Administration deemed the drug a "breakthrough" medication and gave it an expedited review, with approval granted in 2016. It is the only approved drug for Parkinson disease psychosis. But after the federal government received a high number of reports about deaths among patients taking Nuplazid, the FDA last year conducted a safety evaluation of the drug. The agency said it found no "new or unexpected" risks that were not already known at the time of the drug's approval and decided that no further action was needed, *CNN* reported.

However, the ISMP report released Wednesday says documents from the FDA evaluation of Nuplazid fail to answer a number of questions about the drug's safety and efficacy. As a result, the "reassurance" from the FDA was not warranted, according to the medical researchers, safety experts, and doctors who wrote the report.

The FDA refused to comment on the ISMP report. The agency said "in general the FDA does not comment on individual studies or reports, but evaluates them as part of the body of evidence to further our understanding about a particular issue and assist in our mission to protect the public health," *CNN* reported. The maker of Nuplazid, Acadia Pharmaceuticals, has stood by the drug. The company is under investigation by the Department of Justice for its sales and marketing of the medication.

More information: *CNN* Article