



February 16, 2000

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**Sent via e-mail (TITUSS@cder.fda.gov) and Federal Express**

Sandra Titus, Ph.D., Executive Secretary, PDAC  
Center for Drug Evaluation and Research (HFD-21)  
Food and Drug Administration  
5630 Fishers Lane, Room 1093  
Rockville, MD 20857

**Subject: Docket Number 00N-0088**  
Request to Make Oral Presentations at the March 9, 2000 Meeting of  
Psychopharmacological Drugs Advisory Committee Meeting

Dear Dr. Titus:

Janssen Research Foundation is requesting to make two oral presentations at the upcoming March 9, 2000 meeting of Psychopharmacological Drugs Advisory Committee (PDAC). The two presentations (described below), despite the different patient cohorts, evaluation scales, and analytical objectives, each support the concept of a unique psychosis syndrome in dementia according to the three criteria delineated in FDA's position paper (Various Psychiatric and Behavioral Disturbances Associated with Dementia, posted on FDA's website). Because of their fundamental differences however, a combined presentation of these two distinct sets of data would likely prove unnecessarily confusing. Accordingly, we are requesting that Janssen be allotted two separate 10-minute presentation opportunities. This would permit us to present these data in a clear and concise manner, and would assist the Agency's efforts to define this syndrome.

1. **Presentation of Data of Mild to Moderately Severe Alzheimer's Patients in a Community Dwelling Study**

The first 10-minute presentation would be made by Paul Kershaw, M.D., Associate Director of Global Clinical Research and Development, CNS, Janssen Research Foundation. To support the validity of the FDA's proposed criteria for a clinical entity of a psychosis syndrome in dementia, Dr. Kershaw will present data of mild to moderately severe community dwelling Alzheimer's patients that were followed for five months. This patient cohort is analyzed by evaluating the individual items of the Neuropsychiatric Inventory (NPI) scale so that criteria for clinically meaningful psychotic symptoms could be derived and a subgroup of mild to moderately severe Alzheimer's patients suffering from psychotic symptoms could be identified. Analysis is done in these mild to moderately severe placebo-treated patients using the appearance of psychotic symptoms as a

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function of time. Data used in this presentation will also be contained in a written document that will be submitted to the Dockets Management Branch under separate cover.


2. **Presentation of Data of Severely Impaired Dementia Patients in a Nursing Home Study**

The second 10-minute presentation requested would be made by Rick Antonio Martinez, M.D., Director, CNS Medical Affairs, Janssen Pharmaceutica. Using a database consisting of severely impaired dementia patients in a nursing home setting, selected for behavioral disturbances and followed for 12-weeks, Dr. Martinez will also support the proposed criteria for a clinical entity of a psychosis syndrome in dementia. Analysis is made of symptom characteristics by evaluating the individual items of the Behavioral Pathology in Alzheimer's Disease (BEHAVE-AD) scale so that a group of patients suffering from clinically meaningful psychotic symptoms over a two-week period in dementia could be identified. Symptoms and patient characteristics are explored using the criteria proposed by the FDA. Moreover, symptom consistency over time in the placebo-treated group of severely impaired dementia patients will be summarized. Data used in this presentation will also be contained in the written document Janssen will be providing for PDAC's discussion.

We hope you agree that the proposed two 10-minute presentations would allow Janssen's data to be presented in a clear and concise manner, and that you will permit us to make these two separate presentations on March 9<sup>th</sup>.

If you have any questions regarding this request, I can be reached by e-mail at [eturek@janus.jnj.com](mailto:eturek@janus.jnj.com) or by telephone at (609) 730-3328. You may also contact Ms. Victoria Wagner-Weber at (609) 730-3068 or by e-mail at [vweber@janus.jnj.com](mailto:vweber@janus.jnj.com).

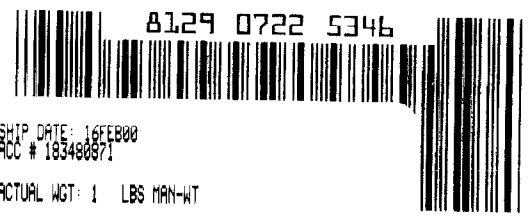
Sincerely,

  
Elizabeth M. Turek  
Director, Regulatory Affairs

CC: Dockets Management Branch, FDA

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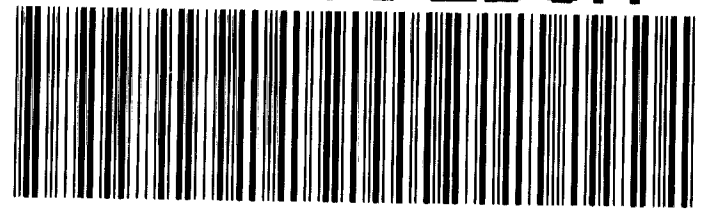
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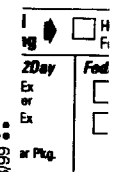
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