JANSSEN • PHARMACEUTICA • • RESEARCH FOUNDATION •

February 16, 2000

0115 '00 FEB 17 A9:16

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 may 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

00N-0088 C 5

JANSSEN AT WASHINGTON CROSSING
1125 TRENTON-HARBOURTON ROAD
POST OFFICE BOX 200
TITUSVILLE, NEW JERSEY 08560-0200

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 9th.

If you have any questions regarding this request, I can be reached by e-mail at 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.

Sincerely,

Elizabeth M. Turek
Director, Regulatory Affairs

CC: Dockets Management Branch, FDA

Federal Express®

Align top of FedEx PowerShip Label here.

FedEx. Express

8129 0722 5346

Form I.D. No. 0205 0103581129 331 WCSL 3/99 PART 154819 Rev. 11/98 ©1994–98 Federal Express Corporation

MAILROOM
JANSSEN PHARMACEUTICA
1125 TRENTON HARBOURTON ROAD
TITUSVILLE, NJ 08560
(609)730-2333

SHIP DATE: 16FEB00
ACC # 1834808?I

ACTUAL WGT: 1 LBS MAN-WT

Sender's FedEx Account Number
1834-8087-1

8129 0722 5346 Form I.D. No. 0205

FedEx. 8129 0722 5346 Form I.D. No. 0205

FedEx Tracking Number — PULL UP PURPLE TAB

100

SEE ADDRESS LABEL ON PACKAGE FOR
THIS SHIPMENT TO MD 20857

8129 0722 5346 FedEx.

8129 0722 5346

REF: B TUREH

PRIORITY OVERNIGHT THU

cad # 0001596 16FEB00

Deliver by:
17FEB00

TRK# 8129 0722 5346 FORM 0201

IAD AA

20857 -MD-US 19 EDGA

153078-077 RIT 08/99

Dockets Management Branch
Food amd Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Time®