CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
21-169

Correspondence

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-169

INFORMATION REQUEST LETTER

JUN 29 2000

FANARI

Janssen Pharmaceutica
Attention: Richard E. Lowenthal
Director, Global CM&C Regulatory Affairs
1125 Trenton-Harbourton Road
Post Office Box 200
Titusville, NJ 08560-2000

Dear Mr Lowenthal:

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for REMINYL (galantamine hydrobromide) Tablets.

We also refer to your submission dated May 25, 2000.

We are reviewing the chemistry section of your submissions and have the following comments and information requests. We need your prompt written response to continue our evaluation of your NDA.

1: We note from your response No I that your acceptance specification for the differs from the same release specification listed in the DMF . and that neither corresponds to the certificates of analysis attached. Please consolidate and edit your specifications for the API so that the acceptance specifications for the API and the release specifications in the DMF reflect the actual analytical findings and are therefore supported by the clinical studies.

2. We note from your response

Please consolidate and edit your specifications for the drug product so they reflect the actual analytical findings related to the clinical batches used in the studies of this application.

If you have any questions, call Melina Fanari, R.Ph., Regulatory Management Officer, at (301) 594-5526.

Sincerely,

6/29/00

Maryla Guzewska, Ph.D.
Chemistry Team Leader, Neurology Drugs for the
Division of Neuropharmacological Drug Products, (HFD-120)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Meta-Drucco

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MAR 21 2000

NDA 21-169

INFORMATION REQUEST LETTER

Janssen Pharmaceutica
Attention: Robin A. Keen
Assistant Director
Regulatory Affairs
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200

Dear Mr Keen:

Please refer to your September 29, 1999 new drug application for Reminyl (galantamine) tablets.

We are reviewing the chemistry section of your submission and have the following comments and information requests. We need your prompt written response to continue our evaluation of your NDA.

1. Please provide the acceptance methods for the API galantamine hydrobromide and the CoAs for the batches used in the manufacturing of REMINYL batches in support of this NDA.

2. Please explain whether your specification for

3. Please either edit your specification for

4. We note your numerous references in your justification of drug product specifications. Please confirm that the API used in support of this application was solely of

5. We do not agree with your desire to call your drug product: REMINYL (galantamine) Tablets and request that you change it to read: REMINYL (galantamine hydrobromide) Tablets.

6. Please provide the proof that the European Pharmacopoeia dissolution apparatus indicated for use in the dissolution tests is equivalent to the USP apparatus.

7.

Please explain.

8. We note that your methods validation package for galantamine hydrobromide frequently use the term in reference to that particular API. Since this particular NDA concerns only galantamine hydrobromide please reedit your MV package.

9. We further notice that your MV package provides for different strength of the tablet. We find that approach quit confusing and request that you edit your MV package and provide us with three copies of corrected edition.

10. Please provide list of samples for MV and the name and address of a contact person.

If you have any questions, call Melina Malandrucco, Regulatory Management Officer, at (301) 594-2850.

Sincerely,

/S/ 3/21/00

Maryla Guzewska, Ph.D.
Chemistry Team Leader, Neurology Drugs for the
Division of Neuropharmacological Drug Products,
(HFD-120)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research