CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
21-224

Correspondence

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Farari

NDA 21-224

INFORMATION REQUEST LETTER

Janssen Pharmaceutica
Attention: Charles A. LaPree
Manager, Regulatory Affairs
1125 Trenton-Harboutron Road
PO Box 200
Titusville, NJ 08560-0200

AUG 14 2000

Dear Mr LaPree:

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) Oral Solution.

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 refer to your NDA 21-169 and our IR letters of June 29 and March 21, 2000 pertaining to that NDA. Please bring your specifications for the REMINYL (galantamine hydrobromide) Oral Solution in line with the specifications for the REMINYL (galantamine hydrobromide) Tablets. Please provide us with the copy of the revised specifications.

2. We request that like in the NDA 21-169 you replace the name galantamine with the full name of the API used in these NDAs, namely galantamine hydrobromide. Please edit your labeling to reflect that change and maintain the full name in all new documents.

3. Also as requested in the NDA 21-169 IR letters please provide in the labeling the drawing of API reflecting its stereochemistry.

4. We note that your specifications for the drug product carry a footnote[

]Please specify which part of specifications it refers to.

5. We find your instructions for the use of the container/closure system difficult to follow (Six operations supported by four drawings). Please simplify your instructions and provide more detailed drawings explaining each operation.

6. We find the provided drawings of the container/closure system not self-explanatory. Please provide more detailed drawings of the container/closure system and explain how the patient is supposed to measure the volume of solution drawn into the pipette.

7. As requested in the IR letter of August 4, 2000 please provide the samples of your container/closure system.

8. We are unable to find your protocol for the in-use stability study, and therefore, can not evaluate the results provided on pp 2/206/207/208. Please provide a detailed protocol for the in-use stability study.

9. For the methods validation, please provide a) list of samples, b) name and address of contact person, c) material safety sheet for API, and d) two additional copies of MV.
If you have any questions, call Melina Fanari, R.Ph., Regulatory Management Officer, at (301) 594-5526.

Sincerely,

[/S/] 8/14/00

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

Fanari

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

1. Please provide us with the samples of your container/closure system for the above drug product.

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

Sincerely,

8/4/00

/S/

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