

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-148

MEDICAL REVIEW



Memorandum

Date: 4/4/00

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From: Saul Malozowski, Medical Team Leader

Subject: NDA 21-148, Norditropin SimpleXx Cartridges. Medical Officer Review and Recommendations

To: The file

Medical Review:

Except for the PK/PD studies where this formulation was compared to the lyophilized Nutropin formulation no clinical data was enclosed for review. Hence the medical has not conducted a formal review but has assisted the biopharm reviewer in the process of evaluating the information. In addition, the MO participated in the internal discussions of the biopharm team and in the final presentation of this data to the supervisors in that discipline. It was concluded, that Nutropin SimpleXx is bioequivalent to Norditropin. As a result, a recommendation for approval was made. I concur with this recommendation.

Due to the paucity of information regarding the potential of local reactions of the new formulation, in a previous document, it was recommended the design of a phase 4 study to assess this issue. Agreements to that effect were reached with the sponsor. Therefore, this issue has been satisfactorily resolved.

DSI Inspections:

Inspections of the site (s) where the studies were conducted were deemed unnecessary, due to the small study size. The MO supported this decision.

Safety Update:

No safety update was required because the biopharm studies were small, self contained and the subjects that were enrolled did not received long term therapy.

ISS:

No integrated safety summary was requested, sent or reviewed. The rationale is the same as above.

ISE:

No integrated efficacy summary was requested, sent or reviewed. The rationale is the same as above.