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APPLICATION NUMBER: 20-450/S-004

MEDICAL REVIEW

MEMORANDUM

NDA 20-450 Cerebyx

FROM: John Feeney, M.D.
Neurology Team Leader

SUBJECT: SLR-004

DATE: August 10, 2001

This supplement provides carton/container labeling to reflect concentration as a function of total container content rather than content per mL. This change was needed because health care practitioners were confusing the amount per mL for the amount per vial and inadvertently giving overdoses to patients.

In our request to the sponsor to alter the labeling, we had initially asked the sponsor to represent _____ . The sponsor later proposed replacing the per mL concentration with the per vial concentration. In part, this was a practical consideration because the small vial size would make it difficult to represent _____ on the label. The division agreed to this in a telecon and the sponsor submitted such labeling.

Unaware of the division's verbal agreement with the firm to only have the per vial concentration represented, Dr. Heimann wrote a chemistry review dated March 18, 1999 which recommended a Not Approvable action. Her recommendation was based solely on the lack of the _____ .

In fact, the division has already verbally agreed to the sponsor's proposed labeling. This decision was correct because the small vial does not allow _____ concentrations and because the _____ could be cause for further confusion in a clinical setting.

Therefore, this supplement should be approved.

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/s/

John Feeney
8/10/01 03:25:34 PM
MEDICAL OFFICER