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RESEARCH**

**APPLICATION NUMBER: 20-667/S-008**

**PHARMACOLOGY/TOXICOLOGY REVIEW**

## Pharmacology/Toxicology Review of Labeling Supplement

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NDA: 20-667  
Drug Mirapex (Pramipexole)  
Supplement: SLR-008  
Date: July 2, 2002  
Reviewer: Paul Roney  
Review Date May 1, 2003

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### Labeling Recommendations

This review examines the sponsor's proposed labeling changes for Mirapex (pramipexole) submitted in labeling supplement SLR-008 on July 2, 2002.

The sponsor is proposing to add language to the label describing the effects of pramipexole on outer nuclear layer of the retina of pigmented rats. The language is an accurate reflection of the findings in these studies. This reviewer has no objection to the revisions proposed by the sponsor. It is recommended that this supplement be approved.

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Paul L. Roney, Ph.D.

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/s/  
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Paul Roney  
5/1/03 09:43:19 AM  
PHARMACOLOGIST

Lois Freed  
5/1/03 10:21:18 AM  
PHARMACOLOGIST