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RESEARCH**

*APPLICATION NUMBER:*

**21-246**

**CHEMISTRY REVIEW(S)**

**SUPPORTING DOCUMENTS:**

NDA 21-087 Hoffman-LaRoche, Inc oseltamivir capsules Chemist's review 1

IND Hoffman-LaRoche, Inc oseltamivir capsules Chemist's review 1

DMF's - See first page of Review Notes Section

**RELATED DOCUMENTS:**

None

**CONCLUSIONS & RECOMMENDATIONS:**

This application, as amended, is in conformance with section 505(b) of the Food, Drug and Cosmetic Act in relation to chemistry manufacturing and controls procedures and may be approved from this standpoint. The product is to carry a 12-month expiration date.

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Dan Boring, R.Ph., Ph.D., Review Chemist for HFD-530

Concurrence:

HFD-530-/SMiller

cc:

NDA 21-087 Original  
HFD-530 Division File  
HFD-830/CChen  
HFD-530/JZheng

HFD-530/DBoring  
HFD-530/SMiller  
HFD-530/JMurray  
HFD-530/NBattula

HFD-530/GCarmouze  
HFD-530/LLewis  
HFD-530/IYuen

29 Page(s) Withheld