# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

**125083Orig1s000**

# OFFICE DIRECTOR MEMO

DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC HEALTH SERVICE
Food and Drug Administration
Center for Drug Evaluation and Research
1401 Rockville Pike
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# Memorandum

Division of Therapeutic Biological Internal Medicine Products
HFM-576

Date: June 1, 2004

From: Marc K. Walton MD, PhD; Director, DTBIMP/ODE6/CDER 6/2/04

Subject: BLA 125083 / 0
Hoffmann-La Roche Pegasys & Copegus Copackaging

To: File STN 125083 / 0

## Introduction

Hoffmann-La Roche (HLR) has submitted this original BLA relating to the combination use of pegylated interferon alfa-2a (Pegasys) and HLR manufactured ribavirin (Copegus) for the purpose of marketing a combined packaged form. Pegasys was first approved as monotherapy for chronic hepatitis C in October 2002 (STN 103964 / 0 ). Pegasys was approved as part of combination therapy for chronic hepatitis C with ribavirin in December 2003 (STN 103964 / 5000 for Pegasys, and NDA 21-511 for HLR ribavirin). Subsequently, the prefilled syringe presentation was approved for marketing in January 2004 (STN 103964 / 5011). These two products have been marketed only as separate packages to the present time, however. HLR has proposed, as the basis for this BLA, to copackage the prefilled syringe presentation of Pegasys with Copegus.

The clinical, preclinical, and CMC reviews for the prior cited approvals of the products should be consulted for all detailed information regarding the products, clinical findings, or recommended manner of their use. No new data has been submitted to support this BLA, and no changes in the approved labeling for these products has been requested, except for container (outer box) labeling, and the "How Supplied" and "Storage" sections of the package inserts. Therefore, there are no clinical data reviews for this BLA. See below for chemistry considerations.

In addition to the prior approvals of professional labeling for these products, it should be noted that both Pegasys and Copegus have FDA approved Medication Guides that are required to be provided to patients each time a prescription is filled.

Additionally, it should be noted that while HLR seeks to market a co-packaged product, HLR has not proposed to discontinue marketing of the individual products.

**Labeling**

HLR has proposed no new professional labeling or Medication Guide or changes to the existing labeling for these products beyond the how supplied section of Copegus labeling to include the 140 tablet bottle. The Storage information in the Copegus labeling will be revised to indicate that storage at refrigerated temperatures is also acceptable.

The labeling of the over-box that will contain both products has been reviewed and the revised version is acceptable.

**Recommendation**

The safety and effectiveness of this combination use product has previously been established. The co-packaging of these products raises no new safety issues, is clear and appropriate informative as to contents and storage. I recommend approval of this marketing application.