CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

125083Orig1s000

PROPRIETARY NAME REVIEW(S)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 125083/0

FEB 13 2004

Hoffmann-La Roche, Incorporated
Attention: Karen Song, Pharm.D.
Program Manager
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Dr. Song:

This letter is in regard to your biologics license application for Peginterferon alfa-2a co-packaged with Ribavirin for the treatment of chronic hepatitis C, BL 125083/0, submitted under Section 351 of the Public Health Service Act.

The Division of Review Management and Policy and the Division of Antiviral Drug Products, in consultation with the Office of Drug Safety (ODS), Division of Medication Errors and Technical Support (DMETS) in the Center for Drug Evaluation and Research (CDER), have reviewed your August 4, 2003 request for proprietary name review and we have the following comment.

> In accordance with 21 CFR Part 201.10 (c), the use of the proprietary name PEGASYS® COPEGUS® (b) (4) Pack is unacceptable (b) (4) (b) (4)

We recommend you consider PEGASYS® COPEGUS® Combination Pack as the proprietary name for this product because this name accurately describes the product. If the use of this proprietary name is acceptable, please submit revised draft labeling to your BLA. If the use of the proprietary name PEGASYS® COPEGUS® Combination Pack is unacceptable, please submit another proprietary name(s) for our consideration. Please include in your request a description of your efforts to verify that the proposed name does not have the potential to cause a medication error due to similarity with proprietary or established names for other marketed product names in either spelling or pronunciation, and submit the results of your study. The submission of an alternate proprietary name should consider not only whether it may be confused with proprietary names for other marketed products with similar spelling or pronunciation but also whether it is false, misleading or fanciful. You will also need to submit revised draft labeling to your BLA.

The regulatory responsibility for review and continuing oversight for this product transferred from the Center for Biologics Evaluation and Research to the Center for Drug Evaluation and Research effective June 30, 2003. For further information about the transfer, please see http://www.fda.gov/cder/biologics/default.htm. Until further notice, however, all correspondence, except as provided elsewhere in this letter, should continue to be addressed to:

CBER Document Control Center
Attn: Office of Therapeutics Research and Review
Suite 200N (HFM-99)
1401 Rockville Pike
Rockville, Maryland 20852-1448

Should you need additional information or have any questions concerning administrative or procedural matters, please contact the Regulatory Project Manager, Karen Winestock, at (301) 827-4358.

Sincerely,

Earl Dye

Earl S. Dye, Ph.D.
Acting Director
Division of Review Management and Policy
Office of Drug Evaluation VI
Office of New Drugs
Center for Drug Evaluation and Research

CONCURRENCE PAGE

Letter Type: Letter: Other (OT)
Summary Text: PEGASYS® COPEGUS® (b) (4) Pack is unacceptable proprietary name

SS & RIS Data Check:
- **If "Unacceptable for Filing" add 2nd LETTER TYPE "UN".**
- **Communication**

RIS Data Check:
- **Submission Screen: In Arrears Box Is Checked**
- **Milestone: Confirm "UN" Entry & User Fees Not Paid -- The Clock Has Stopped. First Action Due Close Date And The New "UN" Entry Date Should Match**
- **No Action Due Date**
- **STN Status – Unacceptable for Filing**

cc: BL 125083/0
M. Walton, HFM-570
K. Ayalew, HFM-582
L. Marzella, HFM-582
C. Syin, HFM-675
R. Fleischer, HFD-530
R. Kambhampati, HFD
D. Birnkrant, HFD-530
J. Murray, HFD-530
T. Sinha, HFD-530
K. Weiss, HFM-500
E. Dye, HFM-589
S. Dallas, HFD-420
C. Broadnax, HFD-42

History: K. Winestock, 1-23-04; 2-11-04: K. Townsend: 2.4.2004: 2.10.2004: 2.11.2004

File Name: Winestock/BLA/125083/tradenameltr

Division	Name/Signature	Date
DRMP	Karen Winestock	2-11-04
DRMP	Schneider	2-13-04
DRMP	Dy	2-13-04
DEMP	Kelly Townsend	2-17-04

CONSULTATION RESPONSE
Division of Medication Errors and Technical Support
Office of Drug Safety
(DMETS; HFD-420)

DATE RECEIVED: August 26, 2003	**DESIRED COMPLETION DATE:** October 24, 2003 **PDUFA DATE:** January 30, 2004	**ODS CONSULT #:** 03-0242

TO: Earl Dye, Ph.D.
Acting Director, Division of Application Review and Policy
HFM-585

THROUGH: Karen Winestock
Project Manager, Division of Review Management and Policy
HFM-585

PRODUCT NAME: PEGASYS® COPEGUS® (b) (4) Pack (Peginterferon alfa-2a Injection 180 mcg/0.5 mL) and (Ribavirin, USP Tablets 200 mg) **BLA#:** 125083/0	**BLA SPONSOR:** Hoffmann-LaRoche, Inc.

SAFETY EVALUATOR: Scott Dallas, R.Ph.

RECOMMENDATIONS:

1. DMETS has no objections to the use of the proprietary name, "PEGASYS® COPEGUS® (b) (4) Pack".

2. DMETS recommends implementation of the label and labeling revisions outlined in Section III of this review to minimize potential errors with the use of this product.

3. DDMAC does not recommend the use of the proprietary name, "PEGASYS® COPEGUS® (b) (4) Pack" from a promotional perspective for the following reason: Claims of (b) (4)

Carol Holquist 1/9/04
Carol Holquist, R.Ph.
Deputy Director
Division of Medication Errors and Technical Support
Office of Drug Safety
Phone: (301) 827-3242 Fax (301) 443-9664

Jerry Phillips 1/9/04
Jerry Phillips, R.Ph.
Associate Director
Office of Drug Safety
Center for Drug Evaluation and Research
Food and Drug Administration