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APPLICATION NUMBER:
125083Orig1s000

ENVIRONMENTAL ASSESSMENT

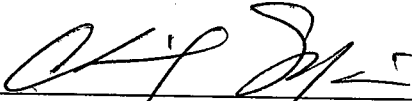


Memorandum

Date: December 10, 2003
From: Chiang Syin, Ph.D., HFD-328
Subject: Categorical exclusion under 21 CFR 25.31 (b)
To: File, BLA STN 125083/0


I have reviewed pertinent sections of the Biologics License Application (STN number 125083/0) from Hoffmann-La Roche Inc., for Peginterferon alfa-2a co-packaged with Ribavirin, and find that their request for a categorical exclusion from an environmental assessment under 21 CFR 25.31 (b) is justified as the estimated concentration of both active moieties at the point of entry into the aquatic environment will be below 1 part per billion, and that no extraordinary circumstances exist that would significantly affect the quality of the environment.

12/10/03
Date


Chiang Syin, Ph.D.
Committee Member
Division of Manufacturing and Product Quality

Concurrence:

12/10/03
Date


Joseph C. Famulare
Director
Division of Manufacturing and Product Quality