



BLA 103145/5098

**SUPPLEMENT BLA APPROVAL  
RELEASE REMS REQUIREMENT**

**June 16, 2011**

Hoffmann- La-Roche, Inc.  
Attention: Ms. Maria Ferrara  
Program Manager, Drug Regulatory Affairs  
340 Kingsland Street  
Nutley, NJ 07110

Dear Ms. Ferrara:

Please refer to your Supplemental Biologics License Application (sBLA), dated March 31, 2011, and received April 1, 2011, submitted under section 351 of the Public Health Service Act for ROFERON-A (interferon alfa-2a, recombinant).

We acknowledge receipt of your risk evaluation and mitigations strategy (REMS) assessment dated January 20, 2011.

This supplemental biologics license application proposes to eliminate the requirement for the approved ROFERON-A (interferon alfa-2a, recombinant) REMS.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

**RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS**

The REMS for ROFERON-A (interferon alfa-2a, recombinant) was originally approved on August 28, 2009. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for ROFERON-A (interferon alfa-2a, recombinant).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of ROFERON-A (interferon alfa-2a, recombinant) outweigh its risks.

Therefore, we agree with your proposal and a REMS for ROFERON-A (interferon alfa-2a, recombinant) is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

**REPORTING REQUIREMENTS**

Furthermore, we remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Abiola Olagundoye, Pharm.D., Regulatory Project Manager, at (301) 796-3982.

Sincerely,

*{See appended electronic signature page}*

/Kendall Marcus M.D./  
for Debra Birnkrant, M.D.  
Director  
Division of Antiviral Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research