

November 14, 2001

Advisors and Consultants Staff
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Regulatory Management
HFD-21, Room 1093
5630 Fishers Lane
Rockville, MD 20852-1734

**SUBJECT: MATERIAL FOR THE ANTIVIRAL ADVISORY COMMITTEE
MEETING DECEMBER 12, 2001**

Dear Sir/Madam:

In response to the Agency letter dated October 30, 2001, Schering is providing for distribution to the Antiviral Advisory Committee 35 copies of the publications based on the results of the hepatitis pivotal clinical trial programs for REBETRON™, PEG-INTRON™ and PEG-INTRON™/REBETOL®. The publications included are:

Rebetron

- Davis GL, et al. Interferon alfa-2b alone or in combination with ribavirin for the treatment of relapse of chronic hepatitis C. N Engl J Med 1998;339:1493-1499
- McHutchison JG, et al. Interferon alfa-2b alone or in combination with ribavirin as initial treatment for chronic hepatitis C. N Engl J Med 1998;339:1485-1492
- Poynard T, et al. Randomised trial of interferon α 2b plus ribavirin for 48 weeks of for 24 weeks versus interferon α 2b plus placebo for 48 weeks for treatment of chronic infection with hepatitis C virus. Lancet 1998; 352:1426-1432

PEG-Intron

- Lindsay KL, et al. A randomized, double-blind trial comparing pegylated interferon alfa-2b to interferon alfa 2b as initial treatment for chronic hepatitis C. Hepatology 2001; 34:395-403

PEG-Intron/Rebetol

- Manns MP, et al. Peginterferon alfa-2b plus ribavirin compared with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: a randomised trial. Lancet 2001; 358:958-965

As the material is copyrighted by the journal in which it was published, it is not being provided electronically.

Please contact Ms. Rachael Steiner (908-740-2565) or Dr. Penny Giles (908-740-2340) for additional information.

Sincerely,

Joseph F. Lamendola, Ph.D.
Vice President
U.S. Regulatory Affairs

RAS/eq