

## **FDA Approves Peg-Intron and Ribavirin Combination Therapy FDA Approval Means Better Treatment Options and More Choices For Patients with Chronic HCV.**

*Alan Franciscus  
Editor-in-Chief, HCV Advocate*

On August 08, 2001 Schering-Plough Corporation announced that the U.S. Food and Drug Administration approved PEG-Intron and Rebetol (ribavirin) for use in patients with compensated liver disease who have not been previously treated with interferon and are at least 18 years of age.

PEG-Intron is a form of pegylated interferon that is injected once weekly instead of standard interferon, which is injected three times a week. Ribavirin is an anti-viral medication in the form of capsules taken daily.

The new combination of medications has been shown in clinical trials to be superior over the combination of standard interferon and ribavirin (Intron A and Rebetol). Twenty-four weeks after treatment ended, 52% of patients treated with Peg-Intron and ribavirin had undetectable levels of virus compared to 46% of the patients treated with standard combination of Intron A and ribavirin--- **a six percent increase.**

The side effects reported with Peg-Intron and ribavirin were similar to those reported with Intron A and Rebetol, with some side effects occurring more often.

Peg-Intron was granted FDA approval in January 2001. Rebetol (ribavirin) was approved by the FDA on July 25, 2001 to market separately as a stand-alone product.

The pricing and marketing availability of Peg-Intron and Rebetol are unknown at this time, according to Robert Consalvo, Director of External Communications for Schering- Plough, but he did state that the products should be available sometime this fall. Consalvo would not speculate whether the products will be sold in a co-packaged or bundled kit, but did say that the products will be available separately.

The approval of this new therapy is **very good** news for patients. Patients have been eagerly waiting for the new combo to be approved, especially those patients who did not respond to previous therapy or relapsed after completion of therapy.

*Source: Company Press Release  
FDA Press Release*