

## Schering Submits Peg-Intron and Ribavirin for FDA Priority Review

*by Alan Franciscus Editor*

Enzon, Inc announced today that Schering-Plough has submitted an application to the Food and Drug Administration (FDA) for marketing approval of Peg-Intron (pegylated interferon) with Rebetol (ribavirin) for the treatment of hepatitis C in patients not previously treated with interferon who have compensated liver disease and are at least 18 years of age. Additionally, Schering has requested a priority review status, which provides for FDA action within 180 days from the date of action.

On January 19, 2001, the FDA granted marketing approval for Schering's Peg-Intron, a once a week injectible medication for the treatment of chronic HCV for patients with compensated liver disease previously untreated with interferon or relapsed following interferon therapy. Schering is expected to market Peg-Intron this month at a wholesale cost of \$962 to \$1,114 for one month's supply.

In November 2000, Schering submitted a supplemental New Drug Application to the FDA to market Rebetol (ribavirin) capsules separately for use in combination with other interferons. This move was expected since FDA approval of Peg-Intron was eminent and would allow Schering to market Peg-Intron with ribavirin separately.

Results from clinical trials reported at AASLD in October 2000 are very encouraging for treating chronic HCV with the combination of Peg-Intron and Rebetol (ribavirin). This study reported an overall 54% sustained virologic response rate. Please see the December 2000 HCV Advocate article 'HCV Treatment Reaches the Next Level' for more information on this study.

The cost of the 'new' combination therapy is expected to draw some fire because of the expected price tag, which could easily top \$2000 a month. However, the patent for Rebetol will expire the end of the year and a generic version could be available which would dramatically lower the cost of ribavirin.

*Source: Business Wire*