



## Food and Drug Administration Licenses First Biologic Product to Prevent Hepatitis B Reinfection in Liver Transplant Patients

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April 6, 2007, The U.S. Food and Drug Administration (FDA) today announced the approval of HepaGam B for the prevention of hepatitis B reinfection in certain liver transplant patients. HepaGam B is the first product of its kind (an immune globulin product) approved for this purpose.

Hepatitis B is a serious disease caused by a virus that attacks the liver and can cause lifelong infection, liver cancer, liver failure and death. Liver transplant patients who have already been exposed to the hepatitis B virus (HBV) are at an increased risk of reinfection because they have weakened immune systems.

"This approval provides a new treatment option for the reduction of hepatitis B recurrence in liver transplant patients with a prior history of this serious disease," said Jesse Goodman, M.D., M.P.H., director of FDA's Center for Biologics Evaluation and Research. "It is the first immune globulin product--one of several classes of proteins derived from human plasma--approved for this use."

HepaGam B works by providing an immediate immune response to the virus. This immunity protects patients previously exposed to HBV. Patients must receive injections at the time of their liver transplant and throughout their lives. This product is manufactured from human plasma collected at U.S. licensed plasma centers from healthy donors.

FDA based its approval on the company's clinical data in a study of HBV-infected persons undergoing full liver transplants, which showed a reduction in the virus recurrence rate from 86 percent to about 13 percent. Adverse reactions were similar to other immune globulin products for other indications and included headache and hypertension.

In January 2006, FDA licensed HepaGam B to prevent infection with HBV for the following other purposes: after acute exposure to blood or certain body fluids containing HBV; perinatal exposure of infants to mothers previously exposed to HBV; sexual exposure to persons previously exposed to HBV; and household exposure to persons with acute HBV infection.

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