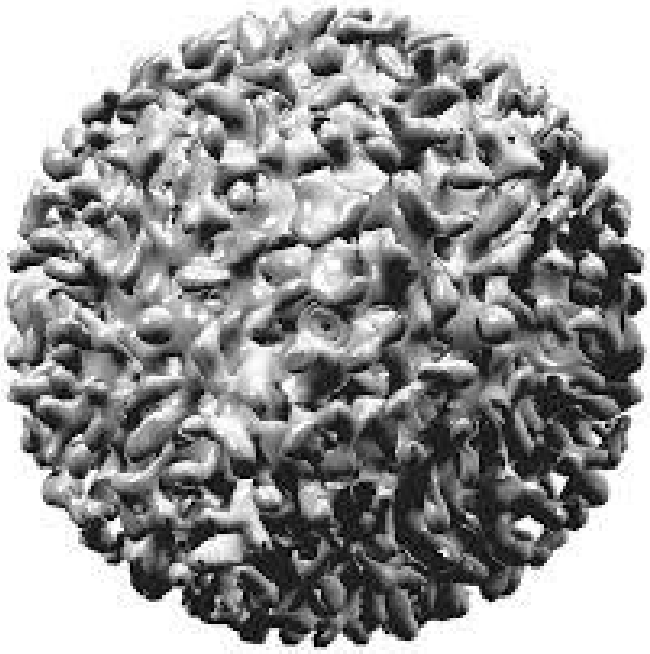
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Breckenridge announces approval of Hep B virus tablets

April 2, 2018 | News

The product is manufactured by RA Chem Pharma Limited and supplied to Breckenridge for exclusive distribution in the United States.



Singapore – Breckenridge Pharmaceutical announced that the U.S. Food and Drug Administration has granted final approval for its Abbreviated New Drug Application for Entecavir tablets USP, 0.5mg and 1mg, a generic version of Baraclude Tablets by Bristol-Myers Squibb Company. The product, which was developed in collaboration with Welding GMBH & Co., is manufactured by RA Chem Pharma Limited and supplied to Breckenridge for exclusive distribution in the United States. Breckenridge will launch the product immediately.

Entecavir tablets (Baraclude) are a Hepatitis B virus nucleoside analog reverse transciptase inhibitor for the treatment of chronic hepatitis B virus infection in adults and children at least 2 year of age. Baraclude generated combined annual sales of $95.9M, according to MAT January 2018 IQVIA sales data.