Nabi hears from FDA
on hepatitis B antibody

Dow Jones Newswires

Boca Raton-based Nabi Biopharmaceuticals announced Wednesday it received a complete response letter from the Food and Drug Administration on the company’s hepatitis B antibody and expects to file its response as soon as possible.

The company, which specializes in developing treatments for infectious and autoimmune diseases, said it plans to submit the response when it completes some statistical analyses. It will comment on the expected timing of the response following more discussion with the FDA.

“This while we prepare our response to the letter from the FDA on the Nabi-HB Intravenous BLA, we’ll finalize important modifications to our Boca Raton plant that will help us to meet European regulatory requirements,” said David Gury, Nabi’s chairman and chief executive officer.

In November, Nabi filed a biologics license application for the device with the FDA. The agency accepted the treatment for priority review in January and was expected to issue a decision this month.

The Nabi-HB intravenous device was designed to prevent reinfection in liver transplant recipients.

A Nabi spokesman declined to comment on the questions raised by the FDA letter and said the meeting with the agency hasn’t been scheduled.

Nabi Biopharmaceuticals (Nasdaq: NABI) traded at $6.86 per share at midday Wednesday, down 39 cents.

FIU business school partners with Hispanic group

Florida International University’s Chapman Graduate School of Business has formed an alliance with the National Hispanic Corporate Council.

Under the agreement, FIU and the NHCC will explore what they termed value-based projects that will capitalize on the complementary skills and assets of both entities.

Joyce J. Elam, executive dean of FIU’s College of Business and the Chapman Graduate School, said the alliance “has the potential to provide our faculty opportunities for new research and our students, more than half of whom are Hispanic, added exposure to corporate America and its needs.”

The National Hispanic Corporate Council is a nonprofit organization dedicated to providing member companies with information, expertise and counsel about Hispanic issues and to advocate for increased employment, leadership and business opportunities for Hispanics in corporate America.