

December 11, 2009

**Subject: HepaGam B[®] (Hepatitis B Immune Globulin [Human] Injection)
Regulatory Status Update**

Dear Healthcare Professional:

Cangene Corporation is providing the regulatory status update as required under the conditions for approval of HepaGam B NOC/c. The NOC/c was issued on January 19, 2007. The status update covers the period from January 2007 to present.

Applicant: Cangene Corporation
Product: HepaGam B, Hepatitis B Immune Globulin [Human] Injection
File Number: 9427-C1449\1-28
Approval Date: January 19, 2007
Prevention of hepatitis B recurrence following liver transplantation in adult patients with hepatitis B who have no or low level of HBV replication.

Commitment Date: January 19, 2007

Annual Status Report of Confirmatory Studies:

Commitment Number: 1
Description of Commitment: Cangene commits to complete the phase 3 clinical trial HB-005 and submit the final study report for Hepatitis B immune globulin (NP-002) for prevention of graft re-infection in hepatitis B related liver transplant patients, within five years following the issuance of the NOC/c.
Study Schedule: Study HB-005 was initiated on March 2004. Initially, the number of patients planned for inclusion was 50. As a result of a mutual agreement between Cangene and the US Food and Drug Administration, the number of patients was changed from 50 to 27 of which two patients were withdrawn for a total enrolment of 25 patients. Last patient last visit was completed on October 3, 2007. Final study report will be submitted to Health Canada upon completion of the study.
Current Status: Clinical study completed. Clinical study report is pending.

Explanation of Status: Study completed enrolment of 25 patients on schedule. All 25 subjects completed the trial with the last patient last visit on October 3, 2007. The study is closed. Final study report will be submitted to Health Canada on schedule i.e. within 5 years following issuance of NOC/c (by January 2012).

Commitment Number: 2

Description of Commitment: Cangene commits to complete the clinical study and submit the final study report of the 1-year extension study to HB-005, study HB-006 within five years following the issuance of the NOC/c.

Study Schedule: Study HB-006 was initiated on April 17, 2007. Clinical activities completed. Last patient last visit was completed on April 29, 2009. Final study report will be submitted to Health Canada upon completion of the study.

Current Status: Clinical study completed. Clinical study report is pending.

Explanation of Status: The study is closed. Final study report will be submitted to Health Canada on schedule i.e. within 5 years following issuance of NOC/c (by January 2012).

Commitment Number: 3

Description of Commitment: Cangene commits to complete the study and submit the final study report for the HB-009 study, examining the safety, pharmacokinetics and efficacy of HepaGam B in combination with antiviral therapy for preventing Hepatitis B recurrence in liver transplant patients in the first year post-transplant.

Study Schedule: Initiate study sites and screening in March 2007. Complete recruitment by June 2009. Complete study report by December 2011.

Current Status: Ongoing.

Explanation of Status: A protocol amendment was submitted to Health Canada on August 10, 2009 and October 29, 2009 outlining modifications to the study design and inclusion criteria.

A two year extension to complete the post licensure commitment was requested by Cangene and granted by Health Canada (HC) which will be captured in a revised Letter of Undertaking to HC. The request for the extension was based on the challenges faced in identifying and enrolling high risk patients in the study, thus causing delays in initiating the study as per the committed schedule.

A No Objection Letter was issued by HC on December 7, 2009 for the protocol amendment. The revised timelines for completing the study are within 7 years following issuance of NOC/c (by January 2014).

Postmarketing Surveillance Commitments

- a. All serious Adverse Drug Reactions occurring in Canada and all serious unexpected ADRs occurring outside of Canada will be reported within 15 days to The Marketed Health Products Directorate in accordance with the current Guidelines for Reporting Adverse Reactions to Marketed Drugs and the Guidance for Industry, Notice of Compliance with Conditions (NOC/c).

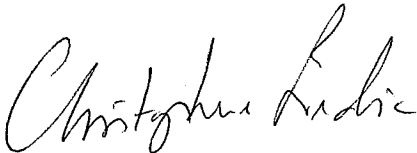
Cangene has been reporting all serious Adverse Drug Reactions (ADRs) occurring in Canada and all serious unexpected ADRs occurring outside of Canada for HepaGam B within 15 days to The Marketed Health Products Directorate (MHPD) in accordance with the current Guidelines for Reporting Adverse Reactions to Marketed Drugs and the Guidance for Industry, Notice of Compliance with Conditions (NOC/c). To date, two serious unexpected ADRs received from the US (US_144848 and US_144851) were submitted to MHPD in an expedited manner.

- b. Periodic Safety Update Reports (PSUR-Cs) to be submitted semi-annually until the conditions have been removed from the NOC/c by Health Canada. PSURs will be prepared in accordance with ICH guidelines.

Cangene has been submitting PSUR-Cs to Health Canada on a semi-annual basis. The PSUR-Cs are prepared in accordance with ICH guidelines. To date, Cangene has submitted two semi-annual PSUR-Cs for the reporting periods July 27, 2008 – January 26, 2009 and January 27, 2009 – July 26, 2009.

Should you have any questions regarding this regulatory update, please do not hesitate to contact me at tel: (416) 675-8281, fax: (416) 675-8301 or email: cfredric@cangene.com.

Sincerely,
CANGENE CORPORATION



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