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November 8, 2005

Robin Biswas, M.D.
US Department of Health and Human Services
Food and Drug Administration
CBER
12420 Parklawn Drive, Room I-23
Rockville, MD 20857

Dear Dr. Biswas:

I am writing on behalf of one of our volunteer donors, Ms. Ruth Petit, who had a biological false positive result for Hepatitis B surface antigen (HBsAg) on her last blood donation. At that time, she was found repeatedly reactive for HBsAg and by the HBsAg neutralization method using the Ortho Clinical Diagnostics – System 3 ELISA assay (OCD-Sys3). Unfortunately, we did not have enough residual sample from the donation samples to perform the alternate GS - HBsAg test by the “shaker method” as required under the “Exceptions and Alternative Procedures” Approved Under 21 CFR 640.120. However, testing performed on a blood sample obtained nineteen months after the HBsAg-reactive donation has been found non-reactive for all hepatitis B markers, including HBsAg (both, by OCD-Sys3 and GS- “shaker method”), anti-HBc, anti-HBs and HBV-DNA by Polymerase Chain Reaction.

A summary of all tests performed is attached for your review. On behalf of Ms. Petit I would like to thank you for taking this request into consideration.

Sincerely,

Germán F. Leparc, M.D.
Chief Medical Officer

GFL:ca

2005M-0270

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TESTING SUMMARY – RUTH PETIT

<u>Sample Date</u>	<u>Test</u>	<u>O.D.</u>	<u>Cut-off</u>	<u>S/C</u>	<u>% Neutralized</u>	<u>Interpretation</u>
11/17/03 (BUN: 4674122)	OCD-3	0.074	0.031	2.387	--	Positive
		0.060	0.026	2.308		
		0.062	0.026	2.385		
	GS-Shaker	N/D	--	--	--	Not Done
	OCD Neut	--	--	--	57.78 %	Positive
	Anti-HBc	0.045	0.594	0.076	--	Negative
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6-20-05 (BUN: 9729981)	OCD-3	0.003	0.024	0.125	--	Negative
	GS-Shaker	Not Available			--	Negative
	Anti-HBc	0.090	0.489	0.184	--	Negative
	Anti-HBs	Not Available			--	Negative
	HBV – PCR	Not Available			--	Negative

Key to abbreviations:

- OCD-3 : ORTHO Antibody to HBsAg ELISA Test System 3
- GS-Shaker : Genetic Systems HBsAg EIA 3.0
- OCD Neut : ORTHO Antibody to HBsAg ELISA Test System 3 – Neutralization Kit
- Anti-HBc : OCD anti-Hepatitis B core antibody
- Anti-HBs : Abbott anti-Hepatitis B surface antibody
- HBV – PCR : Hepatitis B virus by Polymerase Chain Reaction
- N/D : Not Done
- Not Available : Test not performed in-house. Raw data not available (only final interpretation transmitted by laboratory performing the test).