18 May 2004

The Honourable Robert B. Zoellick
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Zoellick

In connection with the signing on this date of the Australia-United States Free Trade Agreement (the "Agreement"), I have the honour to confirm the following understanding reached by the Governments of Australia and the United States during the course of the negotiation regarding treatment to be accorded products derived from blood plasma ("blood plasma products") and blood fractionation services for the production of such products:

1. Any contract with a central government entity of Australia for blood fractionation services in effect on the date of entry into force of the Agreement shall conclude no later than 31 December 2009, or earlier if Australia deems it appropriate.

2. Australia shall undertake a review of its arrangements for the supply of blood fractionation services that shall conclude no later than 1 January 2007. The Commonwealth Government will recommend to Australia's States and Territories that future arrangements for the supply of such services be done through tender processes consistent with Chapter 15 (Government Procurement) of the Agreement.

3. Should the Commonwealth and State and Territory governments reach agreement to make future arrangements for the supply of blood fractionation services through tender processes consistent with Chapter 15, Australia shall withdraw its Annex 15-A, Section 3 reservation regarding the procurement of such services.

4. A Party may require any producer of blood plasma products or supplier of blood fractionation services to fulfil requirements necessary for ensuring the

safety, quality, and efficacy of such products. Such requirements shall not be prepared, adopted, or applied with a view to, or with the effect of, creating unnecessary obstacles to trade.

5. A Party may require that blood plasma products for use in its territory be derived from blood plasma collected in the territory of that Party.

6. Australia confirms that it will not apply any requirement for an applicant for approval of the marketing and distribution of a U.S. blood plasma product to demonstrate significant clinical advantage over Australian-produced products.

7. Article 21.2(c) (Scope of Application) of the Agreement shall apply to paragraphs 1 through 6.

I have the honour to propose that this letter and your letter in reply confirming that your Government shares this understanding shall constitute an integral part of the Agreement.

Yours sincerely

Mark Vaile
Minister for Trade

EXECUTIVE OFFICE OF THE PRESIDENT
THE UNITED STATES TRADE REPRESENTATIVE
WASHINGTON, D.C. 20508

May 18, 2004

The Honorable Mark Vaile MP
Minister for Trade
Parliament House
Canberra ACT 2600

Dear Minister Vaile:

I have the honor to acknowledge receipt of your letter of this date regarding the treatment to be accorded to blood plasma products and blood fractionation services, which reads as follows:

> "In connection with the signing on this date of the Australia-United States Free Trade Agreement ("he Agreement", I have the honour to confirm the following understanding reached by the Governments of Australia and the United States during the course of negotiations regarding treatment to be accorded products derived from blood plasma ("blood plasma products") and blood fractionation services for the production of such products:
>
> 1. Any contract with a central government entity of Australia for blood fractionation services in effect on the date of entry into force of this Agreement shall conclude no later than 31 December 2009, or earlier if Australia deems it appropriate.
>
> 2. Australia shall undertake a review of its arrangements for the supply of blood fractionation services that shall conclude no later than 1 January 2007. The Commonwealth Government will recommend to Australia's States and Territories that future arrangements for the supply of such services are done through tender processes consistent with Chapter 15 (Government Procurement) of the Agreement.
>
> 3. Should the Commonwealth and State and Territory governments reach agreement to make future arrangements for the supply of blood fractionation services under tender processes consistent with Chapter 15 (Government Procurement), Australia shall withdraw its Annex 15-A, Section 5 reservation to that chapter regarding the procurement of such services;
>
> 4. A Party may require any producer of blood plasma products or supplier of blood fractionation services to fulfil requirements necessary for ensuring the safety, quality and efficacy of such products. Such requirements shall

not be prepared, adopted, or applied with a view to or with the effect of creating unnecessary obstacles to trade.

5. A Party may require that blood plasma products for use in its territory be derived from blood plasma collected in the territory of that Party.

6. Australia confirms that it will not apply any requirement for an applicant for approval of the marketing and distribution of a U.S. blood plasma product to demonstrate significant clinical advantage over Australian produced products.

7. Article 21.2(c) (Scope of Application) of the Agreement shall apply to paragraphs 1 through 6.

I have the honour to propose that this letter and your letter in reply confirming that your Government shares this understanding shall constitute an integral part of the Agreement."

I have the further honor to confirm that my Government shares this understanding and you're your letter and this reply shall constitute an integral part of the United States-Australia Free Trade Agreement (the "Agreement"). The United States expects that Australia will undertake any future arrangements for blood fractionation services through tender processes consistent with Chapter 15 (Government Procurement) of the Agreement.

Sincerely,

Robert B. Zoellick