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The Honorable Ambassador Robert E. Lighthizer
United States Trade Representative
Washington, D.C.,
United States of America

Dear Ambassador Lighthizer:

I have the honor to refer to the following understanding between representatives of the Government of the United Mexican States (Mexico) and the Government of the United States of America (United States) reached during the course of the negotiations of the Intellectual Property Rights Chapter of the Agreement.

Mexico and the United States confirm that implementation of "effective market protection" under Article 20.F.14 (Biologics) is without prejudice to a Party's ability to stipulate a period of time during which an application for a follow-on biologic product that relies on the innovator's safety and efficacy data may not be submitted.[1]

I have the honor to propose that this letter, and your letter of confirmation in reply that you share this understanding, both equally authentic in the English and the Spanish languages, shall constitute an agreement between our Governments.

Sincerely,

Ildefonso Guajardo Villarreal

[1] For example, the United States has the Biologics Price Competition and Innovation Act of 2009, which includes relevant provisions at 42 USC 262(k)(7).

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The Honorable Ildefonso Guajardo Villarreal
Secretary of Economy
Mexico City,
Mexico

Dear Secretary Guajardo,

I am pleased to acknowledge your letter, which reads as follows:

> I have the honor to refer to the following understanding between representatives of the Government of the United Mexican States (Mexico) and the Government of the United States of America (United States) reached during the course of the negotiations of the Intellectual Property Rights Chapter of the Agreement:
>
> Mexico and the United States confirm that implementation of "effective market protection" under Article 20.F.14 (Biologics) is without prejudice to a Party's ability to stipulate a period of time during which an application for a follow-on biologic product that relies on the innovator's safety and efficacy data may not be submitted.[1]
>
> I have the honor to propose that this letter, and your letter of confirmation in reply that you share this understanding, both equally authentic in the English and the Spanish languages, shall constitute an agreement between our Governments.

I have the further honor of confirming that my Government shares this understanding and that your letter and this letter in reply, equally valid in the English and Spanish languages, shall constitute an agreement between our two Governments.

Sincerely,

Ambassador Robert E. Lighthizer

[1] For example, the United States has the Biologics Price Competition and Innovation Act of 2009, which includes relevant provisions at 42 USC 262(k)(7).