



THE UNITED STATES TRADE REPRESENTATIVE
EXECUTIVE OFFICE OF THE PRESIDENT
WASHINGTON

November 30, 2018

The Honorable Ildefonso Guajardo Villarreal
Secretary of Economy
Mexico City
United Mexican States

Dear Secretary Guajardo:

I have the honor to acknowledge your letter of this date, which in English reads as follows:

In connection with the signing on this date of the Protocol Replacing the North American Free Trade Agreement with the Agreement Between the United States of America, the United Mexican States, and Canada (the "Protocol"), I have the honor to refer to the following understanding between the Government of the United Mexican States ("Mexico") and the Government of the United States of America ("the United States") reached during the course of the negotiations of Chapter 20 (Intellectual Property Rights) of the Agreement Between the United States of America, the United Mexican States, and Canada:

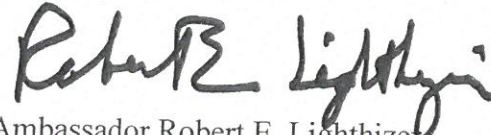
Mexico and the United States confirm that implementation of "effective market protection" under Article 20.49 (Biologics) is without prejudice to a Party's ability to stipulate a period of time during which an application for a follow-on biologic product that relies on the innovator's safety and efficacy data may not be submitted.¹

I have the honor to propose that this letter and your letter of confirmation in reply shall constitute an agreement between Mexico and the United States, to enter into force on the date of entry into force of the Protocol.

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).

I have the further honor to confirm that the United States shares this understanding, and that your letter and this letter in reply constitutes an agreement between the United States and Mexico, which shall enter into force on the date of entry into force of the Protocol.

Sincerely,

A handwritten signature in black ink, reading "Robert E. Lighthizer". The signature is written in a cursive style with a large, stylized "R" and "L".

Ambassador Robert E. Lighthizer
United States Trade Representative