

Brussels, 01. 03. 2017

Dear Ms. Pagán,

I have the honour to acknowledge the receipt of the letter of Ambassador Michael B. Froman dated 19 January 2017 which enclosed the final agreed text of the United States-European Union Amended Sectoral Annex for Pharmaceutical Good Manufacturing Practices (Amended Sectoral Annex) and the Joint Committee Decision amending the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs) signed by the U.S. Trade Representative.

The Amended Sectoral Annex constitutes a sectoral annex to the 1998 Agreement on Mutual Recognition Between the European Community and the United States of America (Framework MRA) and amends and replaces the Sectoral Annex for Pharmaceutical Good Manufacturing Practices done in 1998 (1998 Sectoral Annex).

Pursuant to Article 21 of the Framework MRA, any sectoral annex to the Framework MRA may be amended in writing by the Parties through the Framework MRA Joint Committee decision. In his letter of 19 January 2017, Ambassador Froman informed the European Union that he had signed the Joint Committee Decision, indicating agreement on behalf of the United States to adopt the enclosed Amended Sectoral Annex and confirming that the United States had completed its procedures for entry into force of the Amended Sectoral Annex.

I am pleased to inform you that the European Union has now completed its procedures for the signature of the MRA Joint Committee Decision and the entry into force of the Amended Sectoral Annex. I have accordingly signed the MRA Joint Committee Decision on behalf of the European Union and, with this letter of reply, I am honoured to confirm that the enclosed Amended Sectoral Annex, which amends the 1998 Sectoral Annex and replaces it with a consolidated version, shall constitute an agreement between the United States and the European Union. Pursuant to Article 19 of the Amended Sectoral Annex, it shall enter into force on the date of this letter.

I would like to congratulate the USTR and the U.S. Food and Drug Administration teams for their hard work leading to this important agreement and I am looking forward to continued good cooperation between the EU and U.S. authorities on this matter.

Yours sincerely,


Cecilia Malmström

María L. Pagán
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