

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

January 19, 2017

Commissioner Cecilia Malmstrom
European Commissioner for Trade
European Commission
Rue de la Loi / Wetstraat 200
1049 Brussels
Belgium

Dear Commissioner Malmstrom:

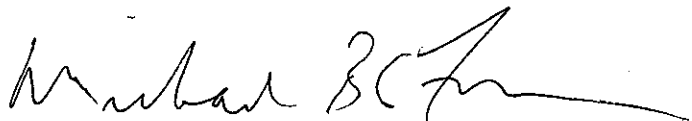
I am pleased to confirm that the enclosed text is the final agreed text of the United States – European Union Amended Sectoral Annex for Pharmaceutical Good Manufacturing Practices (Amended Sectoral Annex). The Amended Sectoral Annex constitutes a sectoral annex to the 1998 Agreement on Mutual Recognition Between the European Community and the United States of America (Framework MRA) and amends the Sectoral Annex for Pharmaceutical Good Manufacturing Practices done in 1998 (1998 Sectoral Annex). The enclosed text shall replace the 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. Accordingly, I have signed the enclosed Joint Committee Decision, indicating agreement on behalf of the United States to adopt the enclosed Amended Sectoral Annex, which amends the 1998 Sectoral Annex and replaces it with a consolidated version.

Signature on behalf of the European Union (EU) of the enclosed Joint Committee Decision and your letter in reply confirming that the enclosed Amended Sectoral Annex is the final agreed text shall constitute an agreement between the United States and the European Union to adopt the enclosed Amended Sectoral Annex, which amends the 1998 Sectoral Annex and replaces it with a consolidated version.

I am also pleased to confirm that the United States has completed its procedures for the entry into force of the Amended Sectoral Annex. Therefore, pursuant to Article 19 of the Amended Sectoral Annex, it shall enter into force on the date of a letter from the EU confirming it has completed its procedures for the entry into force of the Amended Sectoral Annex. I urge the EU to complete its procedures expeditiously to ensure continued progress in the assessment of the Member State authorities.

Sincerely,



Ambassador Michael B.G. Froman
United States Trade Representative