

Decision No 1/2017

of the Joint Committee established under Article 14 of the Agreement on Mutual Recognition between the European Community and the United States of America, amending the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs)

THE JOINT COMMITTEE,

Having regard to the Agreement on Mutual Recognition between the European Community and the United States of America (the "Agreement") done in 1998, and in particular its Article 14 and Article 21; and

Whereas the Joint Committee is to take a decision to amend the Sectoral Annex on GMPs pursuant to Article 21(2) of the Agreement;

HAS DECIDED AS FOLLOWS:

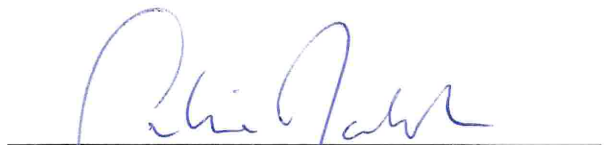
1. Attachment A to this Decision is the United States – European Union Amended Sectoral Annex for Pharmaceutical Good Manufacturing Practices (“Amended Sectoral Annex”) which amends the Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs) done in 1998 and replaces it with a consolidated version.
2. Attachment A has been agreed by the Parties.

This Decision, done in duplicate, shall be signed by representatives of the Joint Committee who, pursuant to Article 21(2) of the Agreement are authorized to act on behalf of the Parties for purposes of amending the Annexes. This Decision shall be effective from the date of the later of these signatures.

On behalf of the United States of America

On behalf of the European Union





Signed in Washington DC, on

January 19, 2017

Signed in Brussels, on

March 1st 2017

Attachment A

Amended Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs)