Brussels, 21 December 2010

To Whom it May Concern,

FDA Approval Pathway for Biosimilar and Interchangeable Biological Products Consultation

EuropaBio, the European Association for Bioindustries and EBE, European Biopharmaceutical Enterprises would like to welcome the opportunity to provide comments to the FDA on this important topic.

We truly believe that a strong regulatory framework, which gives confidence to physicians and patients alike, is the surest way to ensure that biosimilars are an additional treatment option for patients and healthcare professionals. Therefore, we are delighted to share with you some of our experiences linked to the overall very successful EU biosimilar legislative pathway.

Attached, you will find our detailed input to the various questions posed, highlighting EU experience with a particular relevance to the US.

Below, please allow us to highlight a couple of points of particular importance to our members:

1) The generic approach is not applicable to biosimilars
2) A dossier meeting the EU high quality standards is required
3) Neither the European Commission nor the European Medicines Agency can declare biosimilars interchangeable with their reference products
4) European experience shows that guidelines are immensely useful, and we suggest to the FDA to commence work on them as soon as possible, and possibly before the first product approval.

We hope that our input will be of interest and relevance to you and are of course at your disposal, should you require further information on any of the documentation provided.

Yours sincerely,

Nathalie Moll

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