From: Fortunato Giuseppe [Giuseppe.Fortunato@farmabios.net]
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To: ENTR PHARMACEUTICALS COUNTERFEIT
Subject: Public consultation on counterfeit medicines

FARMABIOS S.p.a.

Date May 7 2008

"Farmabios S.p.a." is an Italian company manufacturer of bulk active ingredients for pharmaceutical use. Our customers are important national and international Pharmaceutical Groups and relevant market areas are Europe, USA/America, Far and Middle East.
Farmabios is regularly inspected and authorised by the competent national pharmaceutical agency AIFA and regularly inspected by FDA.

The Company fully agrees with the European Commission's concerns about the introduction into the market of APIs coming from extra-European countries, where the compliance to cGMPs quality standards is not verified by an European Regulatory Authority. The company shares the concerns relevant to such potential risk for human health due to a declared, but not verified "on site" compliance to the requested quality standards (i.e. ICH Q7a).

Therefore Farmabios S.p.a. asks to consider what's requested with the Written Declaration on active pharmaceutical ingredients, approved on November 30th 2006 by European Parliament, more precisely:

1)Introduction of mandatory inspections to manufacturing sites that export APIs into EU, carried out by the European Regulatory Authority.
2)Traceability of APIs in order to identify the source "namely the obligation to indicate the origin of every active ingredient (i.e., Country, company, site of production), in order to avoid relabeling or repackaging of non-EU products".

In conclusion, Farmabios S.p.a. would underline how it is important a change of the current laws in force concerning the medicinal products and the need of preparation o fan over-country legislation, a Community Directive, that rules the matter tightening the requirements for APIs manufacturing.

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