From: Iliopoulos, Theodore [theodore.iliopoulos@polpharma-group.com]
Sent: vendredi 9 mai 2008 11:09
To: ENTR PHARMACEUTICALS COUNTERFEIT
Subject: LEGAL PROPOSALTO COMBAT COUNTERFEIT MEDICINES FOR HUMAN USE

To Whom It May Concern,

The company Polpharma shares the European Commission's concerns related to the introduction into the market of APIs, especially coming from extra-EU countries, that can harm the human health, as not in compliance with the quality GMPs standard, applied in the Community (i.e. ICHQ7A). At present such situations are more and more likely for lacking of the necessary controls.
Therefore the company Polpharma suggests to prepare a legislation, at Community level (that means Directive), which rules the matter. In this way the company Polpharma asks to consider what it's requested with the Written Declaration on active pharmaceutical ingredients, approved on November 30th 2006 by European Parliament, that is: a) mandatory inspections performed by European regulatory Authority on production sites that export APIs into the EU; b) traceability of APIs (i.e. the possibility to locate the source).

Yours Sincerely,
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