From: Pina Anna [A.Pina@adorkem.it]

Sent: jeudi 8 mai 2008 14:48

To: ENTR PHARMACEUTICALS COUNTERFEIT

Subject: Public consultation in preparation for a legal proposal to combat counterfeit medicines for human use

Dear Sirs,

please find enclosed the position of Adorkem Technology S.p.A. concerning the Public consultation in preparation for a legal proposal to combat counterfeit medicines for human use:

The undersigned ADORKEM TECHNOLOGY S.p.A., as manufacturer of APIs in Italy, 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 ADORKEM TECHNOLOGY S.p.A. suggests to prepare a legislation, at Community level (that means Directive), which rules the matter. In this way ADORKEM TECHNOLOGY S.p.A. 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).

Sincerely

Adorkem Technology S.p.A.