From: Fasola Anna [Anna.Fasola@bracco.com]

Sent: mercredi 7 mai 2008 13:21

To: ENTR PHARMACEUTICALS COUNTERFEIT

Subject: PUBLIC CONSULTATION IN PREPARATION OF A LEGAL PROPOSAL TO COMBAT COUNTERFEIT MEDICINES FOR HUMAN USE

To the attention of the European Commission.

The undersigned Bracco 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 Bracco suggests to prepare a legislation, at Community level (that means Directive), which rules the matter.
In this way Bracco 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 and on the supply chain in order to assure the integrity;
b) traceability of APIs (i.e. the possibility to locate the source).
c) transparency for economic operators as to whether wholesalers and other actors in the distribution chain comply with Good Distribution Practice ("**GDP**").

We thank for your support.
Yours faithfully.

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