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**From:** Pallotta, Teresa [Teresa.Pallotta@ZambonGroup.com]  
**Sent:** jeudi 8 mai 2008 16:48  
**To:** ENTR PHARMACEUTICALS COUNTERFEIT  
**Subject:** Public consultation in preparation of a legal proposal to combat counterfeit medicines for human use

Dear Sirs,

This to kindly confirm that the company Zach System SpA, with HQ in Milan - 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 the Zach System SpA suggests to prepare a legislation, at Community level (that means Directive), which rules the matter. In this way the Zach System SpA 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).

Zach System SpA also recommends that the implementing actions for the above mentioned rules are made clear and efficient as soon as applied.

Zach System SpA, a new legal entity inside Zambon Group, is a leading chemical Company with over 600 employees world wide, involved in research & development, manufacturing and marketing of APIs and intermediates for the Custom Synthesis, Contract Manufacturing and Generic Market. Expected 2008 turnover is 140m€, derived from sales mainly focused on the European and US territories.

We remain at your disposal for further information,

With best regards

*Teresa Pallotta*  
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Zambon Advanced Fine Chemicals

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26/05/2008

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