

8<sup>th</sup> May, 2008

To  
Directorate General Enterprise and Industry  
EUROPEAN COMMISSION

Derivados Químicos, S.A. was founded in January 1987, in Murcia (Spain). In 1990, the company started manufacturing and marketing APIs and advanced intermediates for APIs, focusing on great flexibility in the variety of products and size of the productions. Consequently, the company has specialised in the manufacture of chemicals under GMP conditions and according to the clients' demands (custom synthesis).

The company - FDA inspected since 2004 - currently holds the ISO-9001:2000 certification (certification body: AENOR) as well as the ISO-14000 certification.

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Here below please find our considerations with specific regard to European Community document "Public consultation in preparation of the proposal to combat counterfeit medicines for human use - Key ideas for better protection of patients against the risk of counterfeit medicines" and more in particular to paragraph 4.3 "Tightening requirements for manufacture, placing on the market of active substances and inspections".

Derivados Quimicos shares the European Commission's concerns related to the introduction into the market of APIs, mainly of extra-EU countries origin, that can harm human health, being not in compliance with the quality GMPs standard, applied in the Community (i.e. ICHQ7A).

We kindly ask the introduction of mandatory audits carried out by Governmental bodies which would guarantee tight controls thus safeguarding public health.

We therefore suggest to draft a legislation, at Community level (that means Directive), ruling this issue and we would be grateful if you could consider the contents of the Written Declaration on active pharmaceutical ingredients, approved on November 30th 2006 by European Parliament, and more in particular the introduction of (a) mandatory inspections performed by European regulatory Authority on production sites that export APIs into the EU; and ( b) traceability of APIs (i.e. the possibility to locate the source).

In faith,



Jesus Canovas  
General Manager  
Derivados Quimicos