



Treviglio (BG) Italy

Tuesday, May 06, 2008

Dear Sirs,

the company Farchemia S.r.L., part of the International Group Tessenderlo, shares the concerns of the European Commission regarding the introduction onto the European market of APIs coming from non-EU countries. Major preoccupations regard those substances harmful to human health and which are not compliant with G.M.P. standards currently applicable in the EU (ICHQ7A).

Given the present lack of sufficient controls, it is highly likely that a number of these substances are already coming onto the market.

Farchemia S.r.L., therefore, urges the enforcement of legislation at EU level (i.e. via an EU Directive) to implement a ruling on the matter. Farchemia S.r.L. hopes that the provisions of the Written Declaration approved by the The European Parliament on 30th November 2006 will be enforced. Such provision include:

- a) mandatory inspections by European regulatory authorities of those manufacturing sites which export APIs to the European Union,
- b) traceability of APIs by supplying information such as country of origin, company, and production site.

Best Regards,

Sergio Albertazzi  
General Manager  
Farchemia  
Tessenderlo Group

FARCHEMIA, member of TESSENDERLO GROUP



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