Dear Sir or Madam,

Regarding to the new EU directive , “As of 2 July 2013, Any API manufacturer located outside the EU and intending to export bulk API to the EU after 2 July 2013 will be required to obtain from their local competent authorities a ‘written confirmation’ of compliance with API GMP at least equivalent to those in place in the EU. The absence of a written confirmation accompanying a bulk API shipment reaching the EU borders will most certainly lead to this shipment being held/ quarantined by customs.”, as an API manufacture and exporter, we are puzzled:

First, our API has been registered in EDQM, and we have received two EDQM’s successful inspections between year 2004 to 2011, and Germany Bavarian government inspected the facility and the related system in year 2011, and their audit report is shared with EDQM. The inspection results have revealed that our production is strictly following related register documents, and relevant European regulatory requirements. Besides, each batch delivered to customer has been reviewed, tested and released by Import and End user, and they did not raise objections. We do not understand why such written confirmation from national FDA is still required.

Besides, National FDA (Chinese Food and Drug Administration) is an independent government authority, and they are equal with European regulatory authority legally, and each government has their own unique stipulations and stipulations, and it is not easy to be accepted if one government ask the other governments to issue their regulations and operations comply with the other government’s requirements.

Our national FDA did not receive such regulatory requirement till now, and we kindly hope you can communicate with related national FDAs, to evaluate the rationality and feasibility.

Thank you in advance for your attention and best regards,

Lisa

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