London, November 2011
Doc. Ref.: EMA/CMDh/937496/2011

To: Marketing Authorisation Holders (MaHs) / Applicants

Dear Madam/Sir,

Subject: Bio-analytical studies conducted at Cetero Research Houston, Texas (former BA Research)

The US Food and Drug Administration (FDA) has raised some concerns, following its inspection of Cetero Research facilities in Houston (Texas), about the conduct of bio-analytical studies in the period April 2005-June 2010, and has notified pharmaceutical companies that bio-analytical studies conducted by Cetero Research in that period in support of marketing authorisation applications may need to be repeated or confirmed.

The Member States and EMA are undertaking a process to identify all medicinal product dossiers, approved or pending approval, that include studies conducted at the above mentioned facility.

As part of this process, all MAHs and Applicants are requested to provide information on whether the analytical laboratory testing in any of their dossiers was conducted at the CRO Cetero Research Houston, Texas in the defined period.

The following information should be provided:

- The product / active substance and tradename (or proposed tradename where applicable)
- Mutual Recognition number (including additional numbers if it is a variation or line extension etc.) and/or national marketing authorisation number
- Marketing authorisation status as of the time of the reply
- The protocol number/study number(s) as used in the dossier and as used by the laboratory
- The full protocol title
- The test(s) involved
- The start and end date of testing
- The response should cover activities that Cetero Research Houston (Texas) conducted from the period April 2005 onwards till the present.

In case the MAH/Applicant identifies studies conducted between April 2005 onwards till the present at the aforementioned Cetero Research Houston facility in any of their dossiers submitted to National Competent Authorities they are requested to provide information on the following:

- What actions has the MAH/Applicant taken in response to the FDA concerns and what is the outcome?

- Have any problems been identified with the analysis of those studies?

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- Has the MAH/Applicant performed audits, retesting of samples or repeated the study(ies)? If so please provide information.

- What is the importance of the studies conducted at Cetero Research Houston for the dossier and is the potential impact mitigated by other information in the dossier?

- Have you discussed in the application dossier the issues raised by FDA and their impact and if so, in which part of the dossier?

In cases no studies in their dossiers were conducted at the aforementioned Cetero Research facility in Houston the MAH/Applicant should send a response to the National Competent Authorities to this effect.

Please send your responses **to the established contact points at the national competent authorities (see national websites)** with the subject: **CETERO/Name of the product/Name of the Marketing authorisation holder/Name of the Applicant**, no later than the **15th of December 2011.**

Looking forward to hearing from you soon.

Yours faithfully,

Signature on file

Dr. Peter Bachmann
Chair of CMDh