DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

Firm
Attention: Point of contact
Address
City, State, zip code

Dear ANDA Holder/Applicant:

We are writing to you as the sponsor of pending abbreviated new drug application(s) (ANDAs) supported by bioequivalence studies in which the bioanalytical analysis was conducted by Cetero Research at the Houston, Texas site.

FDA has conducted several comprehensive inspections of bioequivalence studies conducted by Cetero Research. The findings of these inspections raise significant concerns about the validity of the reported results of these analytical studies conducted between April 2005 and June 2010 in support of drug applications. Please refer to the Notice for Industry on the CDER website at: http://www.fda.gov/Drugs/DrugSafety/ucm265559.htm.

FDA is contacting you as a holder of pending ANDA(s) to inform you of these issues and what steps you need to take, to demonstrate the bioequivalence of your product(s). Accordingly, with respect to these studies submitted in your application(s), you must amend your application(s) with data derived from one of the following options:

1. New bioequivalence studies.

2. Re-assay the samples from the original BE study. For this option to be accepted, the stability of the analyte in the original samples must be demonstrated throughout the entire frozen storage period.

We are also recommending for all of the above options that the blood/plasma level results obtained in the studies be compared to any published literature or other relevant information that is publicly available.

The new bioequivalence data should be submitted as a bioequivalence supporting document to your pending application(s). Note that pending ANDAs that require amendment with the information described in this letter may not be further reviewed until the necessary bioequivalence data has been received by the Agency. Please find attached the list of your pending applications with studies conducted at Cetero Research during the specified time period. If your company has other applications with studies performed at Cetero Research, Houston during the time period in the FDA letter cited above, that are not on the attached list, you should

consider that this request applies to those applications as well.

If you have any questions regarding this letter, please contact Cecelia Parise, Regulatory Policy Advisor to the Director, Office of Generic Drugs, at 240-276-9310.

Sincerely,

Dale P. Conner, Pharm.D.
Director
Division of Bioequivalence I
Office of Generic Drugs
Center for Drug Evaluation and Research

Firm's ANDAs with studies conducted at Cetero:

ANDA #	Drug	Pending
ANDA #	Drug	Pending
ANDA #	Drug	Pending