U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Moehs Cantabra, S.L. 4/14/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Silver Spring MD 20993

Warning Letter

VIA UPS MAIL

WL: 320-11-01

April 14, 2011

Mr. Xavier Castellsague
Managing Director
Moehs Iberica, S.L.
Poligono Rubi Sur
Cesar Martinell I Brunet, 12A-08191, Rubi (Barcelona)

Dear Mr. Castellsague:

During our December 13-17, 2010 inspection of your active pharmaceutical ingredient (API) manufacturing facility, Moehs Cantabra, S. L. located at Poligono Industrial Requejada, 39313 Polanco Cantabria, Spain, an investigator from the Food and Drug Administration (FDA) identified significant deviations from Current Good Manufacturing Practice (CGMP) for the manufacture of APIs. These deviations cause your API(s) to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 351(a)(2)(B)] in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP.

We have reviewed your firm's response of January 14, 2011 and note that it lacks sufficient corrective actions.

Specific deviations observed during the inspection include, but are not limited, to the following:

1. Failure to investigate and document out-of-specification results obtained for **(b)(4)**, API.

For example, on January 12, 2009, **(b)(4)** lot #**(b)(4)** failed the assay test with an average out-of-specification (OOS) of **(b)(4)**% (specification is **(b)(4)**%) However, your firm released the batch using a passing retest result without conducting an investigation.

In your response you state that the OOS could not be related to the quality of the product because of the individual values obtained (**(b)(4)**% and **(b)(4)**%). Your response is inadequate in that you provided no scientific justification to support your conclusion. All out-of-specification results must be investigated and documented. We are concerned that you released this batch based on a passing retest result without conducting an investigation.

In response to this letter, inform this office of your action plan to correct this GMP deviation.

Please also provide a retrospective review of all API batch analyses that yielded OOS results. Include a complete list of all API batches shipped to the United States since Jan. 1, 2007, with lot numbers, date of shipment, customer name and address, the test value reported to the customer, and all other test results obtained for the lot (including the original OOS result). Also provide your evaluation and conclusions for each of the OOS investigations, and corrective actions to prevent recurrence.

2. Failure to ensure that approved test procedures for **(b)(4)** and **(b)(4)** HPLC are followed.

For example, the inspection found no scientific justification for the current sequence of chromatographic injections performed, which is different to the sequence included in the approved analytical method. Your analytical method requires that **(b)(4)** and then by the injection of the samples to be tested. The inspection found that a different sample and standard sequence was used for the assay analysis of **(b)(4)** lots **(b)(4)** through **(b)(4)**. Although your response to the inspectional observations state that analysts have been retrained, we remain concerned about current laboratory practices, in that not all injection results are being reported. For example, the assay test for lots # failed to include all the injection results performed as part of the chromatographic run. Your response provides no explanation regarding why analytical results are selectively reported.

We are concerned with your firm's overall policy for handling OOS results. In response to this letter, please provide a copy of the investigation concerning the 18 lots of **(b)(4)**, for which you did not follow the HPLC procedure. Please include all individual and average assay results obtained during the assay re-test or re-calculation.

3. Failure to have complete and reliable laboratory control records derived from all tests conducted to ensure compliance with established specifications and standards.

For example, the inspection revealed that your firm lacks raw data of the sample and standard weights used for the HPLC assay of **(b)(4)** and **(b)(4)**. The only record available was an Excel spreadsheet with values entered to calculate the final assay results. In addition, some of the HPLC chromatographs of the lots tested were not included in the batch record.

In your response you acknowledged missing raw data, and stated that all raw data is now required to be maintained and included as part of the batch record. However, you made no commitment to evaluate the extent of the problem and review all previous batches where critical data may be missing.