

# The FDA Warning Letters Report

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| Version 01 | Finished Pharmaceuticals<br>Top Nine Citations in Fiscal Year 2006 –<br>Abstracts of the original wording | Date of Issue:<br>1 November 2006 |
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[211.22 Subpart B – Organization and Personnel  
Responsibilities of quality control unit \(Nr. 1 of the “Top Nine” in FY 2006\)](#)

| Original Wording  | Company /<br>Date   |
|---|---|
| All of the cGMP deficiencies are indicative of your Quality Control Unit's failure to meet requirements impacting the identity, strength, quality, and purity of your drug products [21 CFR 211.22].  | Aquarium Products<br><br>Glen Burnie, MD; 03.05.06                                    |
| Failure of your quality control unit to review production records to assure that errors have not occurred, and to fully investigate errors that have occurred during the manufacturing of your drug products, as stated under 21 CFR 211.22(a). All of the deficiencies stated above are indicative of your quality control unit's failure to assure that each deviation from your drug manufacturing operations, impacting the identity, strength, quality and purity of your drug products, has been adequately investigated. Furthermore, your quality control unit has failed to assure that corrective actions have been determined and implemented to prevent the recurrence of these deviations. | Wyeth<br>Pharmaceutica<br>Is Company;<br><br>Madison, NJ;<br>08.05.06                 |
| The Quality Control Unit lacks adequate laboratory resources (personnel and equipment) for conducting stability testing of drug products [21 CFR 211.22(b)].  | Ranbaxy<br>Laboratories<br>Limited;<br><br>Himachal<br>Pradesh,<br>India;<br>15.06.06 |