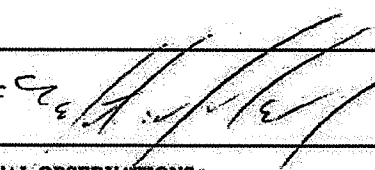


<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> <b>FOOD AND DRUG ADMINISTRATION</b>		
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax: (949) 608-4417 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	<small>DATE(S) OF INSPECTION</small> 10/14/2014 - 10/17/2014 <small>FEI NUMBER</small> 1000519695	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> <b>TO: Patrick A. Thibiant, President &amp; CEO</b>		
<small>FIRM NAME</small> Thibiant International, Inc. <small>CITY, STATE, ZIP CODE, COUNTRY</small> Chatsworth, CA 91311-6026	<small>STREET ADDRESS</small> 20320 Prairie St <small>TYPE ESTABLISHMENT INSPECTED</small> Contract OTC Drug Manufacturer	
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p>		
<p><b>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</b></p>		
<p><b>OBSERVATION 1</b></p> <p>Unauthorized personnel have access to enter areas of the buildings and facilities designated as limited access areas.</p> <p>Specifically, the access to the chemistry, microbiology, and research &amp; development laboratory located in building (b) (4) not limited to authorized personnel.</p>		
<p><b>OBSERVATION 2</b></p> <p>Records of the calibration checks and inspections of automatic, mechanical or electronic equipment, including computers or related systems are not maintained.</p> <p>Specifically, the refrigerator temperature logbooks for the (b) (4) industrial size refrigerators located in the north east corner of building (b) (4) raw material warehouse are not maintained.</p>		
<b>SEE REVERSE OF THIS PAGE</b>	<small>EMPLOYEE(S) SIGNATURE</small> Matthew J. Johnson, Investigator 	<small>DATE ISSUED</small> 10/17/2014
<small>FORM FDA 483 (09/08)</small> <small>PREVIOUS EDITION OBSOLETE</small> <b>INSPECTIONAL OBSERVATIONS</b> <small>PAGE 1 OF 1 PAGES</small>		