

<b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b> PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NUMBER 466 Fernandez Juncos Avenue San Juan, PR 00901-3223 Tel. (787) 729-6854	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Mr. Thomas W. Lapinski		PERIOD OF INSPECTION See remark	C.F. NUMBER 2650141
TITLE OF INDIVIDUAL General Manager		TYPE ESTABLISHMENT INSPECTED Drug Manufacturer	
FIRM NAME Mc Neil Consumer Healthcare Inc.		NAME OF FIRM, BRANCH OR UNIT INSPECTED Same	
STREET ADDRESS Road 183 Km 19.8 Barrio Montones		STREET ADDRESS OF PREMISES INSPECTED Same	
CITY AND STATE (Zip Code) Las Piedras, PR 00771		CITY AND STATE (Zip Code) Same	
DURING AN INSPECTION OF YOUR FIRM I OBSERVED:			
<ol style="list-style-type: none"> <li>The firm's Installation and Operational Qualification report of the Waters Millennium 32 HPLC Computer System does not verify the calculation for the analytical results (manual vs. automatic calculation) as part of the validation.</li> <li>The firm failed to determine the measurement uncertainty for the analytical and microbalances according to USP 24 chapter &lt;41&gt; as for example the determination of minimum weight.</li> <li><del>The firm's analytical laboratory failed to record the temperature of the medium in the individual vessels during the dissolution test.</del> <i>02/13/01 mac 02/13/01</i></li> </ol> <p>The firm lacks to have an effective training program for the laboratory personnel. Approximately 59% and 68% of the out of specification in the analytical laboratory for the years 1999 and 2000 respectively, were analyst error.</p>			
Remarks: Period of inspection: 01/23, 24, 26, 29,30 – 02/05- 08, 13/2000			
SEE REVERSE OF THIS PAGE	EMPLOYEE (S) SIGNATURE <i>Jorge L. Guadalupe</i> <i>Marianela Aponte</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jorge L. Guadalupe, Investigador Marianela Aponte, Acting Investigador (Chemist)	DATE ISSUED 02/13/01