

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION							
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov		<small>DATE(S) OF INSPECTION</small> 10/15/2020-10/23/2020* <small>FEI NUMBER</small> 2000044401					
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Mr. Ankur J. Shah, President							
<small>FIRM NAME</small> Velocity Pharma LLC		<small>STREET ADDRESS</small> 210 Sea Lane					
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Farmingdale, NY 11735-3900		<small>TYPE ESTABLISHMENT INSPECTED</small> Pharmaceutical Drug Repacker/ Relabeler					
<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>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</p> <p>OBSERVATION 1</p> <p>There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.</p> <p>Specifically, the firm has not conducted product specific Filling Process Validation studies for each of the 3 drug products that they package and distribute (Aspirin, Acetaminophen, and Levocetirizine Dihydrochloride Tablets).</p>							
<p>OBSERVATION 2</p> <p>Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.</p> <p>Specifically, the firm has not validated the equipment cleaning procedures, for the (b) (4) Tablet Filler/ Counter (b) (4), used to package Allergy Relief (Levocetirizine Dihydrochloride Tablets), Aspirin and Acetaminophen.</p>							
<p>*DATES OF INSPECTION</p>							
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small> Gam S Zamil, Investigator </td> <td style="width: 40%; vertical-align: top; text-align: center;"> <small>DATE ISSUED</small> 10/23/2020 </td> </tr> <tr> <td style="vertical-align: bottom; text-align: right;"> X </td> <td style="vertical-align: bottom; text-align: center;"> <small>Gam S Zamil Investigator Signed By: 2001625131 Date Signed: 10-23-2020 12:13:43</small> </td> </tr> </table>		<small>EMPLOYEE(S) SIGNATURE</small> Gam S Zamil, Investigator	<small>DATE ISSUED</small> 10/23/2020	X	<small>Gam S Zamil Investigator Signed By: 2001625131 Date Signed: 10-23-2020 12:13:43</small>
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2000044401

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Ankur J. Shah, President

FIRM NAME

Velocity Pharma LLC

STREET ADDRESS

210 Sea Lane

CITY, STATE, ZIP CODE, COUNTRY

Farmingdale, NY 11735-3900

TYPE ESTABLISHMENT INSPECTED

Pharmaceutical Drug Repacker/ Relabeler

10/15/2020(Thu), 10/16/2020(Fri), 10/19/2020(Mon), 10/20/2020(Tue), 10/21/2020(Wed),
10/23/2020(Fri)

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