

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION							
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		<small>DATE(S) OF INSPECTION</small> 2/4/2025-2/6/2025 <small>FEI NUMBER</small> 3017866365					
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Christopher L. Flaxman, Sales Support Team Member							
<small>FIRM NAME</small> ImpactOrtho Inc		<small>STREET ADDRESS</small> 4816 S Ash Ave. , Suite 102					
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Tempe, AZ 85282		<small>TYPE ESTABLISHMENT INSPECTED</small> HCT/P distributor					
<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: OBSERVATION 1 Storage temperatures of HCT/Ps were not recorded and maintained.</p> <p>Specifically,</p> <p>Your firm has not recorded and maintained temperature records for (b) (4) Freezer Serial # (b) (4) and (b) (4) Freezer Serial # (b) (4) since October 2023. These freezers store frozen HCT/P products required to be maintained between (b) (4) per the manufacturer's instructions for use.</p> <p>Additionally, all ambient products stored in your firm's warehouse require temperatures to be maintained between (b) (4)°C per the manufacturer's instructions for use. No temperatures have been recorded by your firm since October 2023.</p> <p>Your firm has distributed (b) (4) frozen and ambient products since October 2023.</p>							
<p>OBSERVATION 2 The quality program has not ensured that appropriate procedures related to core CGTP requirements were established and implemented.</p> <p>Specifically,</p> <p>Your firm has not established a standard operating procedure for investigating temperature alarms,</p>							
SEE REVERSE OF THIS PAGE		<table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;"> <small>EMPLOYEE(S) SIGNATURE</small> Emily S McGann, Investigator </td> <td style="width: 40%; border: none; text-align: center;"> <small>DATE ISSUED</small> 2/6/2025 </td> </tr> <tr> <td style="border: none;"> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> <small>Emily S McGann Investigator</small> <small>Date Signed: 02-06-2025 10:36:10</small> </div> </td> <td style="border: none;"></td> </tr> </table>		<small>EMPLOYEE(S) SIGNATURE</small> Emily S McGann, Investigator	<small>DATE ISSUED</small> 2/6/2025	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> <small>Emily S McGann Investigator</small> <small>Date Signed: 02-06-2025 10:36:10</small> </div>	
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<p>implementing corrective actions, and documenting these actions.</p> <hr/> <p>OBSERVATION 3 Procedures for the maintenance of equipment were not followed.</p> <p>Specifically,</p> <p>Your firm did not perform a qualification for your firm's (b) (4) (b) (4) freezer after (b) (4) (b) (4) in (b) (4) as required by <i>Temperature Monitoring</i> section of your standard operating procedures (SOPs). Your (b) (4) freezers are utilized for storage of frozen HCT/P products.</p> <p>Additionally, both your SOP <i>Temperature Monitoring</i> and the (b) (4) freezer's manufacturer's instructions require alarm checks every (b) (4) days. No alarm checks have been completed and documented since October 2023.</p>			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Emily S McGann, Investigator		DATE ISSUED 2/6/2025
	<div style="text-align: right;"> <small>Emily S McGann Investigator Signed By: Emily S. McGann -S Date Signed: 02-06-2025 10:36:10</small> X </div>		
FORM FDA 483 (09/08)		PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."