DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	10/22/2024-10/29/2024* FEI NUMBER 3017847299

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Gavin R. Webb, President

FIRM NAME	STREET ADDRESS
Legacy Ortho LLC	8460 Duke Blvd Suite 102
CITY, STATE, ZIP CODE, COUNTRY Mason, OH 45040-1577	TYPE ESTABLISHMENT INSPECTED Human Tissue

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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

(b) (4) of HCT/Ps were not recorded.

Specifically,
Your firm does not record (b) (4) for HCT/Ps stored at your facility.

OBSERVATION 2

Procedures appropriate to meet core CGTP requirements for all steps that you perform in the manufacture of HCT/Ps were not established.

Specifically,

Your firm does not maintain procedures for (b) (4) of HCT/Ps.

OBSERVATION 3

Procedures for the (b) (4) of complaints relating to core CGTP requirements were not established.

Specifically,

Your firm does not maintain procedures for (b) (4) complaints.

OBSERVATION 4

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer L Sheehan, Investigator	X Jennifer L Sheehan Investigator Signed By: Jennifer L. Sheehan - S Date Signed: 10-29-2024 07:29:59	10/29/2024

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Procedures including (b) (4) for activities relating to the (b) (4) of HCT/Ps were not established.

Specifically,

Your firm does not maintain procedures for (b) (4) of HCT/Ps.

***DATES OF INSPECTION**
10/22/2024(Tue), 10/29/2024(Tue)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Jennifer L Sheehan, Investigator

X Jennifer L Sheehan
Investigator
Signed By: Jennifer L. Sheehan -S
Date Signed: 10-29-2024
07:29:59

DATE ISSUED
10/29/2024

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."