DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	3/2/2026-3/6/2026
	FEI NUMBER 3001503333

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lourd S. Shlaimon, Director of Quality Systems

FIRM NAME	STREET ADDRESS
IsoTis OrthoBiologics, Inc.	2 Goodyear Ste A
CITY, STATE, ZIP CODE, COUNTRY Irvine, CA 92618-2052	TYPE ESTABLISHMENT INSPECTED HCT/P Processor and Distributor

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

You did not ensure that establishment(s) that by contract, agreement or arrangement, perform manufacturing steps for you were in compliance with applicable CGTP requirements prior to the initiation of the contract, agreement of arrangement.

Specifically,

-Your firm distributed HCT/Ps to firms that were located at (b) (4) (b) (4). None were registered, as required under 21 CFR 1271.10 at the time of distribution.

-Your firm failed to require at least (b) (4) of your consignees to maintain, record, and periodically review storage temperature records of HCT/Ps to make sure that temperature remain within the acceptable limits as specified in product labeling/specifications.

-Your firm has distributed (b) (4) human bone tissue products to these firms from 2017-2026.

OBSERVATION 2

Consignees were not informed in writing at or before the time of distribution of an HCT/P, of the requirements related to HCT/P tracking and the tracking system you have established and are maintaining.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Melsomar R Ramos, Investigator X Melsomar R Ramos Investigator Signed By: MELSOMAR R. RAMOS -S Date Signed: 03-06-2026 16:55:42	3/6/2026

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Specifically,
You failed to inform at least (b) (4) of your consignees in writing about the requirement of establishing a system of tracking Human tissue products.

Your firm has distributed (b) (4) human bone tissue products to these firms from 2017-2026.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Melsomar R Ramos, Investigator

X Melsomar R Ramos Investigator Signed By: MELSOMAR R. RAMOS -S Date Signed: 03-06-2026 16:55:42

DATE ISSUED
3/6/2026

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."