FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

December 26, 2023

Sung O. Park
President
Hans Biomed Corporation
Youseong, 64 Yuseong-Daero 1628 Beon-Gil
Yusung, DAEJEON, 30 Korea (the Republic of)

Dear Mr. Park:

The United States Food and Drug Administration (FDA) conducted an inspection of your firm, Hans Biomed Corporation, located at Youseong, 64 Yuseong-Daero 1628 Beon-Gil, Yusung, DAEJEON, 30 Korea (the Republic of), between August 21 and August 25, 2023. During the inspection, FDA investigators documented significant deviations from the regulations for human cells, tissues, and cellular and tissue-based products (HCT/Ps) set forth in Title 21 *Code of Federal Regulations*, Part 1271 (21 CFR 1271) and issued under the authority of Section 361 of the Public Health Service Act (42 *United States Code* § 264).

The deviations documented on the Form FDA 483, List of Inspectional Observations (Form 483), were presented to and discussed with you at the conclusion of the inspection. These items include, but are not limited to, the following:

1) Failure to document and maintain records of equipment maintenance, cleaning, sanitization, calibration, and other activities performed in compliance with 21 CFR 1271.200 [21 CFR 1271.200(e)]. For example, you failed to document the cleaning and sanitization of a bone saw and (b) (4) bone grinders used in the manufacture of HCT/Ps to prevent the introduction, transmission, or spread of communicable diseases. The bone saw and bone grinders are used during the processing of multiple donors in (b) (4), yet you do not have documentation that this equipment was cleaned between processing sessions.

2) Failure to monitor environmental conditions where environmental conditions could reasonably be expected to cause contamination and cross-contamination of HCT/Ps or equipment, or accidental exposure of HCT/Ps to communicable disease agents [21 CFR 1271.195(c)]. For example, you failed to conduct environmental monitoring of a bone saw and (b) (4) bone grinders used in the manufacture of HCT/Ps to prevent the introduction, transmission, or spread of communicable diseases. The bone saw and bone grinders are used during the processing of multiple donors in (b) (4) yet you do not have documentation that this equipment was cleaned between processing sessions.

3) Failure to maintain records concurrently with the performance of each step required in subparts C and D of 21 CFR 1271. All records must be accurate, indelible, and legible. The records must identify the person performing the work and the dates of the various entries and must be as detailed as necessary to provide a complete history of the work performed and to relate the records to the particular HCT/Ps involved [21 CFR 1271.270(a)]. Failure to maintain records of the use of each piece of equipment, including the identification of each HCT/P manufactured with that equipment [21 CFR 1271.200(e)]. For example, your "Cortical-Powder/Chip Batch Record" does not include documentation of steps 8-10 that are outlined in section 6.2.1 of the Standard Operating Procedure, SOP-06.400.39, "SureBone Production Process" (revised 02/20/2023). You do not maintain records of the technicians performing bone cutting, and you failed to document the equipment and supplies used in processing steps 8-10.

The deviations identified above are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all applicable requirements of the federal regulations. You are responsible for reviewing your firm's operations as a whole to ensure that you fully comply with the law.

Please notify us in writing within thirty (30) working days from the date you receive this letter of the specific steps you have taken to correct the noted deviations and prevent their recurrence. If you do not believe there is a basis for the regulatory issues raised in this letter, include your reasoning and any supporting information for our consideration. Your response should be sent to the following address: CBERDCMRecommendations@fda.hhs.gov. If you have any questions regarding this letter, please contact the Division of Case Management, CBER at (240) 402-9156. Please be advised that only written communications are considered official.

Sincerely,

Melissa J. Mendoza
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Cc: (b) (6)