



Certificate No. CT:UGU5-TAB3

Application Number: 0810-23

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Rocky Mountain Tissue Bank, located at 2993 S. Peoria Street Suite 390, 2993 S. Peoria Street Suite 390, Aurora, CO 80014, USA, manufactured and distributed the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Product Name

Irradiated Allogenic Cancellous Particulate (CANPAR)

Irradiated Allogenic Cortical Particulate (CORPAR)

Irradiated Allogenic Cortical/Cancellous Block Grafts (BB)

The product(s) described above and the establishment(s) where it is produced are subject to FDA jurisdiction and regulated solely under section 361 of the Public Health Service Act (PHS Act) and regulations promulgated thereunder. The company listed above has certified to the FDA that the HCT/P meets the requirements of FDA regulation, Title 21, Code of Federal Regulations Part 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products.

It is certified that the above listed HCT/P may be marketed in, and legally exported from, the United States of America at this time. The company listed above is subjected to periodic inspections. The last inspection showed that the plant(s) at that time, appeared to be in compliance with the requirements of FDA regulation, Title 21, Code of Federal Regulations Part 1271.

Signature _____

Robert A. Sausville
Director
Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration

This certificate is valid from April 24, 2023 to April 23, 2025.

