Gmail

Laurie Coppola <lauriecoppola@gmail.com>

RE: 2017-2441 BMAC

Industry.Biologics <Industry.Biologics@fda.hhs.gov> Mon, Dec 11, 2017 at 3:39 PM
To: "lauriecoppola@gmail.com" <lauriecoppola@gmail.com>

Dear Ms. Coppola,

Thank you for your patience. As stated previously, you inquiry was forwarded within CBER to the Office of Tissues and Advanced Therapies (OTAT). They provided the following information:

FDA regulates human cells, tissues, and cellular and tissue-based products (HCT/Ps), defined as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include bone, ligament, skin, dura mater, heart valves, cornea, tendon, oocytes, semen, and hematopoietic progenitor cells (HPCs) derived from peripheral and umbilical cord blood (UCB). In accordance with 21 CFR 1271.3(d)(4), **minimally manipulated bone marrow** for homologous use and not combined with a drug or a device is not considered an HCT/P, and is not regulated by FDA. The Health Resources and Services Administration (HRSA) has oversight of minimally manipulated bone marrow from unrelated donors. This oversight is executed through the Bone Marrow Coordinating Center, a component of the CW Bill Young Cell Transplantation Program, by contract with the National Marrow Donor Program (NMDP). Minimally manipulated bone marrow for homologous use that is not combined with another article and is for autologous or related use is not subject to Federal oversight.

Further information on the Bone Marrow Coordinating Center is available here:

http://bloodcell.transplant.hrsa.gov/ABOUT/Legislation_and_Contracts/BMCC/index.html.

Sincerely,

Pauline
Consumer Safety Officer

Center for Biologics Evaluation and Research
Office of Communication, Outreach and Development,

Manufacturers Assistance and Technical Training Branch
U.S. Food and Drug Administration

Tel: 240-402-8020 or 800-835-4709
Industry.Biologics@fda.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: Industry.Biologics
Sent: Thursday, November 30, 2017 7:43 AM
To: Laurie Coppola <lauriecoppola@gmail.com>
Subject: RE: 2017-2441 BMAC

Dear Ms. Coppola,

Thank you for your inquiry. The Center for Biologics Evaluation and Research (CBER) is one of seven centers within the Food and Drug Administration (FDA). CBER is responsible for the regulation of biologically-derived products, including blood intended for transfusion, blood components and derivatives, vaccines and allergenic extracts, human cells, tissues, and cellular and tissue-based products (HCT/Ps), gene therapy and xenotransplantation products.

Your inquiry was forwarded within CBER to the Office of Tissues and Advanced Therapies (OTAT). A response will be provided as soon as it becomes available. I appreciate your patience during this process.

If you have additional questions or want to follow up on the status of the response, please contact me at the Manufacturers Assistance and Technical Training (MATT) Branch within CBER. The MATT branch provides assistance to industry, including small manufacturers, and responds to requests for information regarding CBER policies and procedures.

Sincerely,

Pauline
Consumer Safety Officer

Center for Biologics Evaluation and Research
Office of Communication, Outreach and Development,

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From: Laurie Coppola [mailto:lauriecoppola@gmail.com]
Sent: Wednesday, November 22, 2017 12:20 PM
To: Industry.Biologics <Industry.Biologics@fda.hhs.gov>
Subject: 2017-2441 BMAC

Does CBER consider centrifuged bone marrow aspirate an HCT/P? And if so is it regulated under section 361 of the PHS act?

Thanks,

Laurie Coppola