DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Ombudsman
5600 Fishers Lane
Room 14B-03, HF-7
Rockville, MD 20857

Food and Drug Administration
Rockville MD 20857

March 11, 2002

Mr. Robert Churinetz
Senior Vice President
Global Operations
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: Request for Designation
Allomatrix™
Our file: 2001.020

Dear Mr. Churinetz:

The Food and Drug Administration has completed its review of Wright Medical's request for designation covering Allomatrix™. The request was filed by this office on July 17, 2001. On August 10, 2001, Wright extended the designation deadline for this request to provide the agency with sufficient time to fully consider the issues raised. The agency met with representatives of Wright on September 24, 2001, and Wright supplemented its RFD with additional information on October 17 and 25, 2001, and January 14, 2002.

Allomatrix™ consists of human demineralized bone matrix (DBM), [redacted] Allomatrix™ is marketed in a kit containing DBM, [redacted] During surgery, the surgeon mixes the dry components [redacted] turning the dry ingredients into putty. The putty is placed in bone voids to induce bone formation. It is used whenever a physician requires the use of demineralized bone as an allograft material.

The [redacted] are added to DBM in order to make it into a putty. Dry, powdery DBM could migrate out of the graft site; the putty is moist, malleable, easy to handle, and stays in position once the surgeon places it in the patient. Wright characterizes [redacted] as excipients. Wright states further that the [redacted] do not provide a matrix that allows bone to grow into it; according to Wright, the [redacted] have no effect on the formation of new bone.

Wright argues that Allomatrix™ is a human tissue product that may be regulated solely under section 361 of the Public Health Service Act and 21 CFR Part 1271 rather than the drug or device provisions of the Federal Food, Drug, and Cosmetic Act (the Act). After extensively considering the matter, including meeting with representatives of Wright Medical and reviewing several supplemental submissions by Wright, the agency concludes that Allomatrix™ does not meet the all the criteria for regulation solely under section 361 of the Public Health Service Act and 21 CFR Part 1271.

On January 19, 2001, FDA issued a final rule called Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing.[1] Among other things, this rule listed four criteria that must all be met for human cells, tissues, and cellular and tissue-based products (HCT/P's) to be regulated solely under section 361 of the Public Health Service Act.[2] These criteria are:

1. The HCT/P is minimally manipulated;
2. The HCT/P is intended for homologous use only;
3. The manufacture of the HCT/P does not involve the combination of the cell or tissue component with a drug or device, except for a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the HCT/P; and
4. Either:
    - i The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
    - ii The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
        - a. is for autogolous use
        - b. is for allogeneic use in a first or second degree relative; or
        - c. is for reproductive use.

Allomatrix™ does not meet the third criterion for regulation solely under section 361 of the Public Health Service Act. As Wright has explained, the [redacted] are added to demineralized bone with the intention of affecting the structure or function of the body – that is, to make demineralized bone easier to handle and to hold the demineralized bone in place at the bone void site. Accordingly, the agency concludes that within the meaning of 21 CFR 1271.10(a)(3), Allomatrix™ combines an HCT/P with a drug or device that is not a sterilizing, preserving, or storage agent. Therefore, Allomatrix™ is not eligible to be regulated solely under section 361 of the Public Health Service Act, but instead is regulated under the Federal Food, Drug, and Cosmetic Act. Further, consistent with the agency's review and regulation of other products containing DBM and having similar composition and mode of action, Allomatrix™ is appropriately

[1] See the Federal Register of January 19, 2001 (66 FR 5447).
[2] 21 CFR 1271.10(a).

reviewed and regulated under the medical device premarket notification provisions of the Act.

We are aware that other currently marketed demineralized bone products may also fail to meet the third criterion that HCT/P's must meet in order to be regulated solely under section 361 of the Public Health Service Act. In the very near future, the Center for Devices and Radiological Health will notify you, and all other known manufacturers of similar products, of the requirements for bringing such products into compliance with the Act. If you would like to discuss these requirements in the meantime, please call Mr. Mark Melkerson, Deputy Director, Division of General, Restorative and Neurological Devices at 301-594-1184.

If you have any questions about this matter, please call Suzanne O'Shea, of this office, at 301-827-3390.

Sincerely,

Suzanne O'Shea for

Steven H. Unger
Ombudsman