Aventis Pharmaceuticals

April 30, 2001

Via fax and UPS

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. 97N-484P
Draft Guidance for Industry on Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement

Dear Sir/Madam:

Aventis Pharmaceuticals is pleased to have the opportunity to comment officially on the " Draft Guidance for Industry on Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement" in response to the Federal Register notice of January 8, 2001. While we agree with many of the recommendations given in the Draft Guidance, we offer the following comments for your consideration.

(I. Introduction)

"the agency is proposing to regulate under the authority of section 361 of the PHS Act and not as biological drugs or devices"

How does this impact the classification and submission of tissue-device products if these combination products are regulated under Section 361 of the PHS Act and what will be the criteria or basis for a single or multiple Center (CDER/CBER/CDRH) review?

(IB. The Tiered, Risk-Based Regulatory Approach)

" Certain human cellular and tissue-based products (e.g. tissues that are more than minimally manipulated) would be regulated as biological drugs or medical devices under the Federal Food, Drug and Cosmetic Act (the Act) and/or section 361 of the PHS Act (42 U.S.C. 262), and thus would be subject to premarket review procedures, among other requirements."

" FDA is proposing to regulate other human cellular and tissue-based products solely under the authority of section 361 of the PHS Act (42 U.S.C. 2640, which authorizes the agency to issue regulations to prevent the introduction, transmission, or spread of communicable diseases.(These products are referred to in this document as "361 products") "

"FDA anticipates that determining the regulatory process for certain cellular and tissue-based products may be complicated. To help answer questions about how a particular cellular or tissue-based product will be regulated, the agency developed the Tissue Reference Group(TRG)"

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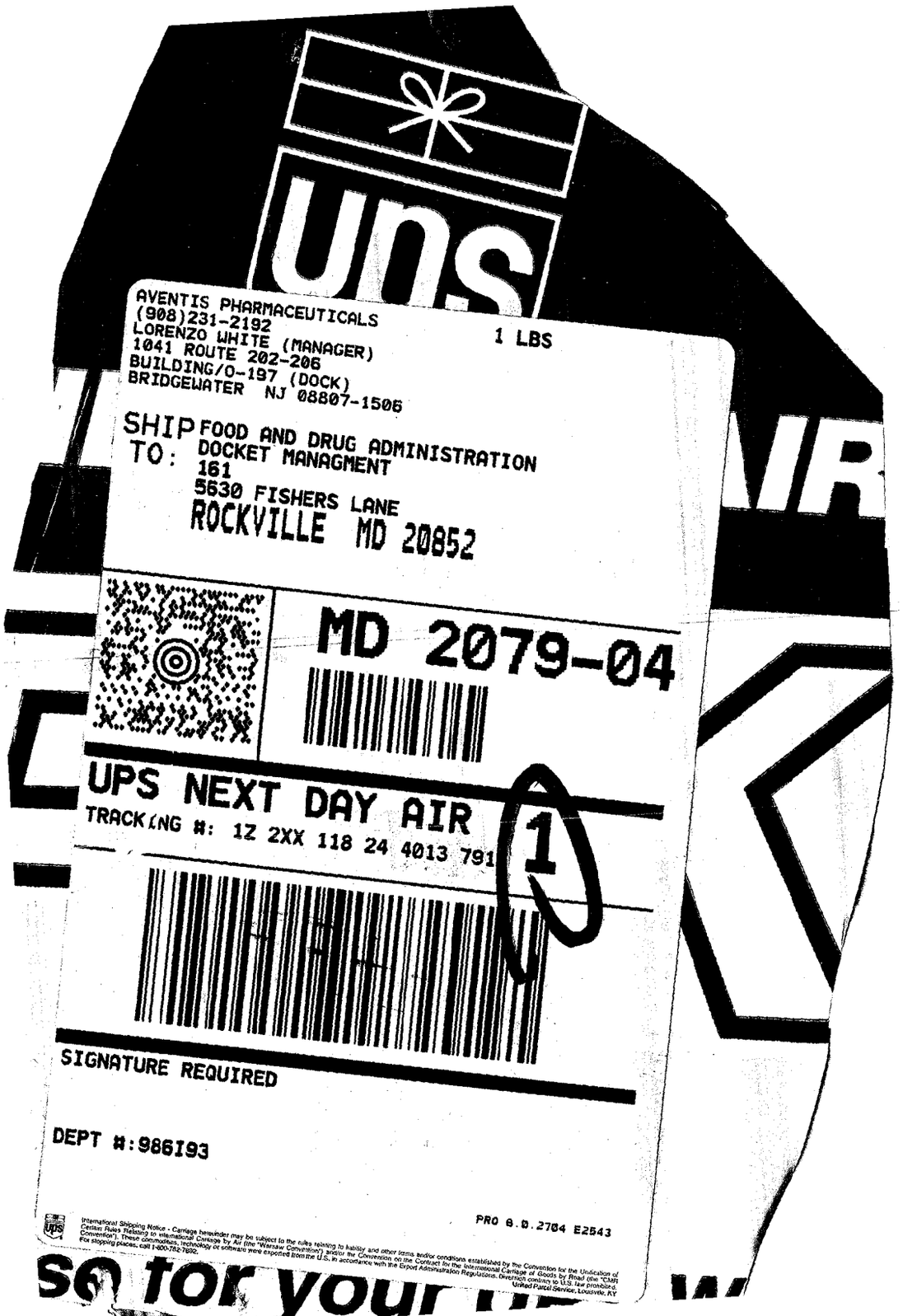
Given this proposed classification scheme, on what physiological/biochemical basis will the TRG decide whether a product will be reviewed by a single Center or will be reviewed jointly by more than one Center? Currently, combination products may be classified for Center review based on their predominate or primary mechanism of action either as a drug, biologic or device. This implies that a combination product could require a PMA, NDA, BLA or ELA/PLA. The proposed rule does not specify how the agency Centers will harmonize the regulation for a combination biologic/drug/device product where there may be more than one mechanism responsible for its efficacy/safety (i.e. controlled/sustained release implantable pumps). On what scientific basis will they distinguish the non-361 from the 361 products?

On behalf of Aventis Pharmaceuticals, we appreciate the opportunity to comment on "Draft Guidance for Industry on Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement" and thank you for your consideration.

Sincerely,

James Boyd

James Boyd, Ph.D., MBA
N.A. Regulatory Center Head
Global Drug Regulatory Affairs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