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May 30, 2003

Mark B. McClellan, M.D., Ph.D.
Commissioner, U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857-0001

Re: FDA's Interpretation of the Drug and Device Definitions and Section 503 of the Act (Combination Products)

Dear Dr. McClellan:

You will recall that I sent you a letter on April 1, 2003 (enclosed). It stated my client and I had learned the Agency might be prepared to determine whether a product is a drug or device, or a drug-based or device-based combination product, based on criteria different than those that were enacted in the Safe Medical Devices Act of 1990 (SMDA). The letter explained the situation in some detail, and asked you to confirm that the Agency would follow the intent of congress. This matter arose from the Agency's review of a Request for Designation submitted by one of my clients (RFD 2003.038).

We continue to be concerned about all the issues described in my April 1 letter, but we had assumed you would not respond to that letter before the Agency had made a final decision concerning the specific RFD under review. We have received the Agency's initial decision, and it is now undergoing reconsideration. (Both the initial decision, and our request for reconsideration are enclosed.) Regrettably, the initial response to the RFD suggests that the Agency may indeed be unwilling to follow the statutory rules.

Specifically, we have the new concern that the Agency might avoid a determination that my client's device is a combination product only because it appears to strengthen the Agency's current position that the product should be regulated as a drug; and, we continue to be concerned that the Agency intends to misinterpret the definition of a device so that it can regulate devices as drugs when it chooses to do so.

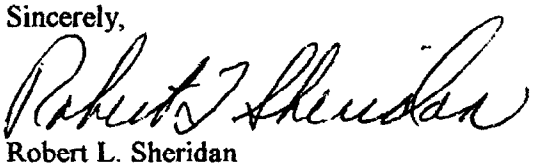
The FDA's initial response asserts that a device-like regulated article can have more than one primary purpose. It notes that the statute expressly uses the plural form of the term "purpose" in the definition of a device. Presumably, the Agency wants to regain the right to regulate as a drug those devices that have a device-like primary purpose but also have an important but non-primary use as a drug – a right it had prior to the SMDA. FDA clearly does not want to recognize that congress intended the definition of a device to be consistent with Section 503(g) of the FDCA. Even from a logical point of view, the

Agency should realize its statement is untenable and counterproductive. The plain meaning of the term "primary," which was added by SMDA, means "first in importance." We are not aware of how two or more distinguishable uses of a product can be "first in importance."

The Agency's initial response also notes that a single product can have both a drug and a device function. The Agency's letter then notes that my client's product has a device function, and then says but because it "...also functions as a drug, these physical functions do not make it a device." We, of course, had understood all along that a product with both a drug and device function is not automatically a device. But it was our understanding that such an article would be a combination product, a fact the Agency denies elsewhere in its response to the RFD.

As noted in my earlier letter, this issue is important to the device industry and, I presume, to the congress. Thus, I have updated both Ms. Pamela Bailey, President of Advanced Medical Technologies Association, and Mr. Mark Paoletta, Chief Counsel for the Subcommittee on Oversight and Investigations, House of Representatives, about the developments to date (letters enclosed). I will, of course, notify them as to the final outcome of this matter; not to inform them about whether my client's product is treated as a drug or device, but to clarify how such a determination is ultimately made.

Sincerely,



Robert L. Sheridan

Enclosures: April 1, 2003 letter to Dr. McClellan
FDA's initial decision on RFD 2002.038
May 27, 2003 Request for Reconsideration
May 27, 2003 letter to Ms. Bailey
May 27, 2003 letter to Mr. Paoletta