

RE: Docket No. 2004N-0194
www.fda.gov/OHRMS/DOCKETS/98fr/04-10447.pdf

The comments of Cambrex BioScience Walkersville address the definitions of a drug and device mode of action.

Specifically the rule would define that a “constituent part has a device mode of action if it meets the definition of device contained in section 201(h)(1) to (h)(3) of the act (21 U.S.C.321(h)(1) to (h)(3)), *it does not have a biological product mode of action*, and it does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and is not dependent upon being metabolized for the achievement of its primary intended purposes. Proposed 21 CFR 3.2(k)(2). A “constituent part has a drug mode of action if it meets the definition of drug contained in section 201(g)(1) of the act *and it does not have a biological product or device mode of action.*” Proposed 21 CFR 3.2(k)(3). 69 Fed Reg. 25527, 25528 and 25532, May 7, 2004. Emphasis supplied.

Primary mode of action (PMOA) is not currently defined in the Act or regulations.

The traditional drug definition, and the statute itself, does not restrict drug or device products to those without a biological product or device mode of action. In fact, in the many decades after the Public Health Service Act was passed drugs and devices with biological components have been regulated as drugs and devices in the respective Centers, including reproductive and endocrine drugs and interactive wound dressings. Hyaluronic acid (HA) is also biologically derived and regulated as a drug or device, depending on its use. The proposed rule does not address this change nor the economic impact of the change in policy. Further, the proposed rule does not address how this determination would affect these products regulated in other Centers. Although it states the rule would apply prospectively and presumably the Agency is not including a proposal to move products from those Centers under 21 CFR 3.9, it does not address the disparity nor the impact, economic or otherwise, that would be created by having some products remain regulated in their historical Centers and follow on products regulated in other centers, presumably under other statutory authorities.

In this letter we also incorporate the arguments of Advamed made in their letter to FDA’s Daniel Troy of August 20, 2002 regarding the impact of this change.
www.advamed.org/publicdocs/81502troyltr.pdf.

By this language, a combination with an inactive or clearly secondary biological component would never be a drug or a device. This result renders any product with a biological component a biological product, regardless of the primary mode of action of the combination as a whole and regardless of its affect on the therapeutic action of the product. This is inconsistent with the enabling statute, inconsistent with the stated purpose of the rule, and inconsistent with past decisions in this area.

In order to assure consistency with past decisions, and between like products, we thereby request the removal of the language that would make the biological mode of action the primary mode regardless of its affect on the therapeutic action.

Thank you for the opportunity to submit our comments.

Respectfully submitted,

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