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May 14, 2004

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

***RE: Docket No. 2004D-0001: GHTF Study Group 1 Document: Information Document  
Concerning the Definition of the Term "Medical Device"***

Dear Sir/Madam:

AdvaMed, the Advanced Medical Technology Association, is pleased to provide the following comments on the GHTF document, Information Document Concerning the Definition of the Term "Medical Device." AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,100 members and subsidiaries manufacture nearly 90 percent of the \$75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the \$175 billion purchased annually around the world.

AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have fewer than \$30 million in sales annually.

**Section 5.0 Harmonized Definition of the term "medical device"**

Note 3

AdvaMed is concerned with the inclusion of Note 3 which implies that accessories should be regulated at the same level of the parent device, especially as it relates to in vitro diagnostics. Note 3 states: "accessories intended specifically by manufacturers to be used together with a parent medical device to enable that medical device to achieve its intended purpose, should be subject to the same GHTF guidance as it applies to the medical device itself." Also, Section 6.2 of the document, "Principles of Medical Device Classification contains an identical statement.

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Such guidance has broad implications and may subject hundreds of accessories to more stringent controls than are necessary. Countries with developing regulatory systems that adopt the GHTF definition of accessories may require greater regulatory oversight of accessories than is necessary. Determining which accessories enable a medical device to achieve its intended purpose is open to wide interpretation and may result in divergent regulatory schemes rather than harmonized systems.

Accessories used with vitro diagnostic devices (IVDs) illustrate this point. Typically, IVDs consist of instrument systems and the reagents, which are used on these systems. The instrument systems and reagents are parent devices, regulated under appropriate controls. Accessories to such systems vary by instrument type and reagent type. These accessories are intended by the manufacturer to be used with the instrument systems and reagent kits to achieve the intended purpose of the device. Often these accessories are general purpose articles such as laboratory equipment used to perform the in-vitro diagnostic assay. The following represent just a few examples of accessories to IVD instruments and reagents: activator diluents, autoloader rack, bar code scanner, bottle septum, centrifuge tubes, cuvettes, diluent cap, drying bath seals, filters, graduated cylinders, incubators, luer-lock caps, micro-pipettes, multi-assay manual diluents, optic standards, O-ring wash, pipettes, pneumatic tubing set, reaction cells and trays, sample cups, sample holder, sample loader racks, shakers, syringes, transfer efficiency kits, tubing, vials, wash buffers and solutions, water baths. Many of these accessories would not require the same level of regulatory oversight as the parent device nor should such articles be classified separately as a medical device.

In addition to accessories used with IVD instruments and reagents, there are examples of accessories used with other medical devices that should not necessarily be regulated at the same level as the parent device. For example, a drill bit or reamer could be classified as Class I if used with a manual drill and Class II if used with a power drill. A pacemaker lead adaptor may not be regulated at the same level as the pacemaker lead.

Applying Note 3 to these accessories would require each country adopting the document to determine which accessories it will regulate and depending on the parent device, which level of regulatory control will be applied. This approach would be extremely complex and burdensome and add unnecessary cost and regulation. We therefore, believe that Note 3 is not needed and recommend its deletion from the "definition" document and further recommend a similar modification of section 6.2 of the "Principles of classification" document to reflect the change.

AdvaMed appreciates the opportunity to provide these comments.

Sincerely,



Janet Trunzo  
Senior Vice President  
Global Regulatory Affairs

cc: Maurice Freeman