



Corporate Regulatory and Quality Science

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

RE: Global Harmonization Task Force, Study Groups 1, 2, 3, and 4;
New Proposed and Final Documents [Docket 2004D-0001]

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding the following two Global Harmonization Task Force (GHTF) draft guidance documents published in the Federal Register on February 18, 2004 at 69 FR 7650: (1) "Information Document Concerning the Definition of the Term 'Medical Device,'" dated March 26, 2003 and identified with document number SG1/N029R13 and (2) "Principles of Medical Devices Classification" dated December 16, 2003 and identified with document number SG1/N015R22.

Through the development of recommended procedures and guidance documents, the Global Harmonization Task Force (GHTF) is shaping the global regulation of medical devices. As intended, countries developing or modifying their medical device regulations are relying upon the guidance provided by the GHTF. In evaluating new work projects, the GHTF Operating Procedures recommend considering, "what negative effects may result...the addition of unnecessary steps in getting a product on the market, increased costs for the manufacturer or the regulator..." (GHTF Operating Procedures, GHTF/AHPG/N3R8: 2000, Sept. 21, 2000, page 8).

It is equally important for the GHTF to consider what negative effects may result from its endorsed positions provided in final guidance documents. Specifically, we are concerned with the negative effects that will result from the GHTF recommendation to regulate medical devices accessories at the same level as the medical device itself. This recommendation can be found in GHTF documents "Information Document Concerning the Definition of the Term 'Medical Device,'" (March 26, 2003 Number SG1/N029R13) and "Principles of Medical Devices Classification," (November 17, 2003 Number SG1/N015R22).

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Given the broad spectrum of medical devices and the wide variety of country regulations, we appreciate the enormity and the difficulty of developing a harmonized definition of the term "medical device." Equally difficult is addressing those products for which there is not yet a harmonized approach. These products are captured in Note 2 of the guidance document "Information Document Concerning the Definition of the Term Medical Device." Included within this list are accessories for medical devices ("accessories").

Unlike the other products identified under Note 2, additional guidance is provided on the regulation of accessories. This guidance, which is provided in Note 3, states, "[a]ccessories 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 applies to the medical device itself." An identical statement is included in Section 6.2 of the document, "Principles of Medical Devices Classification." The "Principles of Medical Devices Classification" guidance document further states, "[f]or classification purposes an accessory may be classified as though it is a medical device in its own right."

We strongly urge the GHTF to reconsider the guidance it is providing in regards to the regulation of medical device accessories. Such guidance has broad implications, subjecting hundreds of accessories to more stringent controls than necessary. Requiring more stringent controls than necessary for accessories, adds to the cost of medical devices and to the health care system as a whole. Countries adopting the GHTF definition of accessories will require greater oversight and resources to regulate accessories. Given the global influence of the GHTF, unnecessary oversight and regulation of accessories is significant, resulting in increased costs for regulators and manufacturers and the addition of unnecessary steps in getting a product on the market.

Further, determining which accessories enable a medical device to achieve its intended purpose is open to wide interpretation. Which accessories and how they will be regulated will vary from country to country. Divergent regulation is unavoidable.

Under such an approach, trays designed to hold surgical implants would be regulated at the same level as the implants, Class C or D. Would reusable surgical instruments, such as drill bits, calipers, and forceps, which are classified as Class A under the GHTF system be regulated as Class C or D when they are used during procedures to implant devices classified as Class C or D?

These points are further illustrated with accessories to *in vitro* diagnostic devices (IVDs). 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. Attachment 1 provides examples of some of the accessories to IVD instruments and reagents.

Applying Note 3 of the guidance document to these accessories would require each country adopting the document to determine which accessories it will regulate. Further, it would require each country to regulate the accessories at the same level as the parent



device, which will vary depending on the reagent system. Manufacturers, such as Abbott, would be required to maintain various levels of regulation, from technical files to labeling, on each accessory, as determined by each country. Such an approach is extremely complex and burdensome for regulators and industry, does not further global convergence, and moves away from consistent, economic, and effective control of medical devices. In short, such an approach adds unnecessary cost and regulation.

For these reasons, we strongly urge the GHTF to reconsider its position on the regulation of medical device accessories by removing Note 3 from the guidance document defining medical device and modifying the "Principles of Medical Devices Classifications" document accordingly.

Should you have any questions, please contact me at (847) 937-8197 or by facsimile at (847) 938-3106.

Sincerely,

A handwritten signature in cursive script that reads 'April Veoukas'.

April Veoukas, J.D.
Associate Director, Regulatory Affairs
Corporate Regulatory and Quality Science
Abbott Laboratories

Cc: Ginette Michaud,
GHTF Study Group 1
Office of In Vitro Diagnostic Devices (HFZ-440)
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850



Attachment 1: Examples of Accessories to IVDs

Acid	Optical Injection/Metering Syringe
Acridinum	Optical Solutions
Activator Concentrates	O-Ring Wash
Activator Diluents	Peristaltic Pump Tubing
Activator Line Treatments	Photometric Reading Tubes
Air Deflector	Pipette Check Solution
Allen Wrench	Pipettes
Aperture	Pneumatic Tubing Set
Aperture Brush	Power Cord
Aperture Plate	Pre-trigger Solutions
Aspiration Probe Tubing	Prime/Purge Accessories
Assay Modules	Priming Solutions
Assay Software	Printer
Autoloader Rack	Printer Cable
Bar Code Labels	Printer Paper
Bar Code Scanner	Printer Stand
Bleach Wash Bath	Printout Tickets
Bottle Septum	Probe Cleaning Solutions
Cap Piercer	Rack Completion Indicators
Centrifuge Tubes	Reaction Cells
Check Valve	Reaction Trays
Concentrated Wash Buffers	Reaction Vessels
Counting Cups	Reagent Line Kit
Cover Slips	Reagent Line Tubing
Cuvettes	Rinse Kit



Data Station Cable	Sample Aspiration Tubing
Detergent Cap	Sample Cartridges
Detergent Line Inlet Assy	Sample Cups
Diluent Cap	Sample Holder
Diluent Line	Sample Injection Syringe
Diluent Syringe	Sample Loader Racks
Dilution Buffers	Sample Probe
Dispensers	Sample Probe Assembly
Drain Hose	Sample Probe Clip
Drying Bath Seals	Sample Tubes
Dura Clamps	Serial Loopback Device
EDTA Capillary Tubes	Shakers
Enzymatic Cleaner	Solenoid Ring Pull
Facilitator's Guide	Student Training Guides
Fan Filter Material	Substrate Diluents
Fan Guard	Substrate Solutions
Filters	Syringes
Fuses	System CD-ROM
Graduated Cylinders	System Diluents
Graphics Printer Paper	System Disk
Graphics Ribbon	Teal Line Filter
Impedance Injection/Metering Syringe	Temperature Cyclers
Inactivation Diluents	Transducer
Incubators	Transfer Efficiency Kits
Installation Guides and Checklists	Transfer Efficiency Washes
Interface Cable	Transfer Pump



Keyboard

Keyboard Cover

Latex Particles

Line Cleaners

Lint Free Pads

LIS Loop-Back Connector

Luer-Lock Caps

Lyse Cap

Lyse Line Inlet Assy

Lyse Syringe

Matrix Cell Wash

Matrix Cells

Micro-Pipettes

Monofilament Nylon Stylet

Multi-Assay Manual Diluents

Optic Standards

Trigger Solutions

Tube Deflector Brush

Tubing

Tubing Decontamination Solutions

Vent Needle

Vials

Wash Block

Wash Buffers

Wash Solutions

Waste Bottle Cable

Waste Cap Assy

Waste Dummy Plug

Waste Line Outlet Tubing With Sensor

Waste Sensor

Waste Sensor Dummy Plug

Water Baths