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AdvaMed
Advanced Medical Technology Association

September 24, 2001

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

Re: Docket No. 01D-0281

The Advanced Medical Technology Association (AdvaMed) is pleased to provide comments on the Food and Drug Administration (FDA) draft guidance document, "A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Draft Guidance for Industry and FDA Staff". AdvaMed (formerly the Health Industry Manufacturers Association) represents more than 800 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $68 billion health care technology products consumed annually in the United States, and nearly 50 percent of $159 billion purchased around the world annually. The proposal, a Summary Technical Documentation for Demonstrating for Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED), was developed by Study Group 1 of the Global Harmonization Task Force (GHTF) comprised of representatives from the United States, Canada, European Union, Australia, and Japan.

General Comments:

Benefit to industry of a harmonized registration submission
Medical device companies have learned to work within the current country and region-specific registration schemes by taking the same information for a device and placing it into the unique country-specific format. If companies could create one core dossier for all submissions for all countries comprising the GHTF, then the process for assembling and submitting the information would be less time-consuming and more efficient. The STED would provide sufficient data to all regulatory agencies and thereby demonstrate that additional requirements above and beyond the STED are not needed. If, however, countries still require information in addition to that submitted in the STED, then the benefit to industry would be greatly diminished and the goal of harmonization would not be fully realized. In order to achieve harmonization in situations where a specific country requires information

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beyond the STED such as completion of validation studies or inclusion of specific Quality Systems documents, we recommend the use of promissory statements that the validation studies will be complete prior to marketing or that the Quality Systems documents will be maintained at the company. AdvaMed believes that harmonization could ultimately lead to reduction in both the overall review times around the world and the resources required for submissions.

Use of the STED format for Premarket Notification (510(k)) and Premarket Approval (PMA) submissions

FDA's pilot includes both 510(k) and PMA products and the GHTF document implies that the full STED should be used for all classes of devices. Some of the information required by a full STED, such as manufacturing process description, is not currently submitted for 510(k)s. Although the GHTF has not reached a position on the threshold for devices that would not need to have the STED submitted, AdvaMed is concerned that the use of the STED for all types of devices, may lead to rising standards for low risk devices. In addition, we are concerned that harmonization may lead to inclusion of quality systems information in 510(k) and PMA submissions. The STED examples, provided in the appendices of the GHTF STED document, contain the following information: conformance to ISO standards, information about quality assurance systems, the firm's quality systems documentation on areas such as design and manufacturing, and manufacturer's testing documentation and test reports. As a general rule for most submissions to FDA, this type of information is not required. AdvaMed expressed its opposition to the inclusion of quality systems information in submissions in comments submitted to FDA November 1, 1999 (copy enclosed) regarding the draft Guidance on Quality Systems Regulation Information for Various Premarket Submissions (Docket Number 99D-2212). Quality Systems compliance can only be assessed through audits, not through a paper review of Quality Systems documents.

For Class I and II devices requiring a 510(k) submission, AdvaMed recommends that the items in the STED that are not required for a 510(k) be marked as "Not Applicable (N/A)" or by some other method of indicating items not required. This would still make the STED usable for both domestic and foreign submissions.

Additionally, the requirements for Class II and III devices in Canada do not require submission of most of the information in the STED. This could be handled in the same manner as we recommend above for the 510(k). AdvaMed does not support the inclusion of information in a submission that is only required to be on file at the company. The overall impact of the STED should be to decrease the amount of time/effort of registering products, not to increase it.

Incentives for manufacturers to submit a STED

The FDA proposed pilot program contains no immediate incentives for manufacturers to submit a STED for review in lieu of the standard 510(k) or PMA/PMA Supplement. Some of the devices listed by FDA as eligible for the pilot program are also eligible for third party review. AdvaMed supports the third party review program and has encouraged its

membership to participate in the program when applicable. Therefore, we encourage FDA to reconsider the devices eligible for the STED pilot program. In addition, the full STED requirements would not allow manufacturers to file early as some do now in that the STED requires summary of validation testing and some manufacturers file 510(k)s prior to validation. To address this concern, AdvaMed recommends the use of promissory statements in the STED that the validation testing will be complete prior to marketing.

For PMA submissions in the pilot, FDA still requires the sponsor to submit 2 applications—the customary format of the PMA in addition to the STED. Therefore, a reviewer would be reviewing 2 submissions instead of one, and the submitter would have to prepare 2 documents. AdvaMed is concerned that PMA review times will increase in this situation. In today's competitive marketplace, companies cannot afford longer FDA review times. If FDA is serious about including PMAs in the pilot, then it should develop a review process whereby a reviewer is not reviewing the same information twice—once in the traditional PMA and again in the STED.

If other countries are conducting the pilot during the same period as FDA and with the same devices, then one incentive for the company to participate in the pilot is that the STED submission could be used for submissions made to the other countries. In this way, the company would save time and resources and the pilots for all the countries could be evaluated and compared. It may not reduce the review times, but it will reduce the time and resources required to prepare and submit applications. This would represent a major incentive to manufacturers.

Focus of FDA's pilot program

AdvaMed recommends that the pilot program focus on high risk 510(k)s, original PMAs and PMA Supplements—the requirements for these submissions are closer to those in a STED. In this way, FDA can equitably evaluate the suitability and adaptability of the STED format. Furthermore, AdvaMed is concerned by the limited participation of DCRD and DGRND in the pilot program as submissions for the devices in these divisions are more like a STED.

Success Measures for the pilot program

In order to evaluate the effectiveness of the program, the same set of measures for success/failure of the pilot should be identified for all countries conducting the pilot. FDA should clearly define the criteria and analysis methods before the pilot program is initiated.

Concurrent pilot programs in participating countries

The pilot programs should be run at the same time with the same devices and conducted in the same manner in all major countries. If the pilot is run this way, the program can be appropriately evaluated to determine if the harmonized format is more efficient and leads to faster approvals.

Four of the founding members of the GHTF (US, Canada, Australia, and the European Union) plan to pilot the program. Each country should select the same device categories for pilot eligibility. Australia plans to pilot the program from June, 2001 to December, 2001, which does not run concurrently with FDA's pilot. Furthermore, the eligible devices under Australia's pilot are different than those eligible for FDA's pilot. AdvaMed suggests that the four regions harmonize the pilot by running it simultaneously and including the same device categories. The commitment to evaluate the program in concurrent time periods is essential to the success of this endeavor. In addition, we recommend that the GHTF post information on each pilot on its web site so that companies can easily access information about each country's procedures and expectations.

Changes to current laws and regulations
If the various governments agree to adopt the STED format, law and regulation changes may be needed to allow implementation of the approach. This could represent the biggest stumbling block, especially for countries having additional requirements beyond those in the STED. Also, some countries developing regulations, and those countries not participating in the pilot study, may also need to change their laws and regulations. However, some countries may be able to accommodate the STED through administrative discretion and application of existing general, non-prescriptive rules.

Specific Comments:

Format Suggestions of the STED Working Draft Document
AdvaMed recommends clarification of the format for a STED defining exactly the type of information/data that is needed to supplement the responses to each of the essential principles. Also, we recommend further clarification on the need to address every essential principle, regardless of the device class. It appears that each essential principle (and sub-principle) must be addressed for low risk and high risk devices.

In Section 7.4 of the GHTF STED document, the required labeling information includes the instructions for use. In Table 2 of FDA's pilot document, section 7.4 is referenced without any changes. FDA's draft guidance for labeling (Medical Device Labeling - Suggested Format and Content, 4/25/97) refers to these documents as "Information for Use" rather than "Instructions for Use". The actual instructions for use are contained in one section of the Information for Use. AdvaMed recommends that FDA clarify these terminology differences in the final guidance for harmonized submission formats.

Clarifications in the Guidance Document

AdvaMed recommends that FDA clarify the following items in the guidance document:

- Content of the STED, PMA, 510(k)

It is unclear whether FDA expects to see the same information in the PMA or 510(k) as in the STED and whether FDA believes this is an issue of formatting or different content requirements. We recommend that the same information be provided in the PMA or 510(k) as in the STED.

- Supporting data requirements

  Occasionally different tests or details of supporting data are provided to FDA vs. other regulatory bodies. Therefore the generic use of the term "supporting data" may not apply similarly to all agencies. The guidance document should clarify which supporting data, i.e., biocompatibility reports, can be harmonized.

- IDE data

  It is unclear how the use of IDE data from a previous IDE-supplement will be used towards supporting a PMA-supplement if the original data was not provided in the format of STED.

- Clinical study reports

  For clinical study reports, varying levels of detail/summary data may be required by the five countries/regions. In addition, while a 6-month follow-up for a particular study may be required for a PMA approval by the FDA, similar clinical data may not be required to obtain approval in Japan or in Europe. If clinical data is part of the core STED, but is not required for that country, then timelines for approval in that country may increase as it reviews this additional information.

- Labeling

  Label and language requirements vary among the countries covered by the GHTF proposal. If labeling were included in the core STED, it is unclear which labels/which languages would be submitted.

- PMA Supplements

  It is not clear whether FDA intends to include PMA supplements in the program as the guidance only refers to "PMA applications." AdvaMed believes that PMA supplements should be included in the pilot program.

- Use of Standards

  Because the STED relies heavily on standards, the guidance document should refer to FDA's list of recognized standards and FDA's process for accepting additional standards.

- Section IV, page 5

  The bulleted lists and tables are confusing because the list implies that these additional items are not part of the STED, while the table implies that they are part of it (i.e. "cover page information" and "country-specific information" which are, per the table heading, considered a section of the STED).

  The table refers to "Annexes" while the STED calls them "Appendices."

  It is not clear why some of the items are not captured in the cover page or country-specific sections—specifically Indications for Use Enclosure.

  It is not clear whether FDA expects manufacturers to include all STED information in the pilot submission. Under Table 2, FDA states "Section 7.6 of the draft GHTF STED document, which addresses manufacturing information, is ordinarily not required for a 510(k) submission." AdvaMed agrees that manufacturing information is not required for a 510(k) submission and believes that this information should not be included for 510(k) devices in the pilot.

- Section IV, page 5-6

  The bulleted list for PMAs is unnecessary as all items are included in Table 3.

AdvaMed appreciates the opportunity to provide comments on FDA's draft guidance document on its proposed pilot program to evaluate a harmonized approach to premarket submissions.

Sincerely

Janet Trunzo

Janet Trunzo
Vice President
Technology and Regulatory Affairs

JT/ts

Enclosure (1)

H I M A
HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

November 1, 1999

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

Re: Guidance on Quality System Regulation Information for Various Premarket Submissions (Docket Number 99D-2212)

Dear Sir or Madam:

The Health Industry Manufacturers Association (HIMA) hereby submits its written comments on the draft guidance entitled "Guidance on Quality System Regulation Information for Various PreMarket Submissions" (Draft Guidance). The Notice of the Draft Guidance's availability was published in the *Federal Register*. See 64 Fed. Reg. 42137 (August 3, 1999).

HIMA is the largest medical technology trade association in the world. It represents more than 800 member firms that manufacture medical devices, diagnostic products and health information systems. HIMA members provide nearly 90 percent of the $62 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $147 billion purchased annually around the world.

HIMA appreciates the opportunity to comment on the Draft Guidance and recognizes its purpose is to provide the medical device industry with FDA's current thinking on information that it believes applicants should include in their premarket approval applications (PMAs) and Product Development Protocols (PDPs), and information that firms should maintain at their manufacturing sites for premarket notifications (510(k)s). However, it is HIMA's position that the Draft Guidance is inappropriate in that it 1) violates FDA's Good Guidance Practices; 2) exceeds the authority provided to the Secretary of Health and Human Services under the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act); 3) exceeds or misinterprets the requirements of the Quality System regulation; and 4) diverts FDA's limited resources away from statutory mandated activities.

HIMA requests that FDA and the medical device industry jointly develop a regulatory scheme that complies with the intent of Congress, and that is mutually acceptable to both FDA and the industry.

I. The Draft Guidance Violates FDA's Good Guidance Practices

FDA's Good Guidance Practices published in the February 27, 1997 *Federal Register*, (62 Fed. Reg. 8961, 8963) state:

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> The only binding requirements are those set forth in the statute and FDA's regulations. Under the Administrative Procedure Act (Sec. 10.40(d)), in order to bind the public, FDA must (with limited exceptions) follow the notice and comment rulemaking process.

FDA violates its own policy on page 3 of the Draft Guidance when it says:

> PMA and PDP submissions should include a complete description of design controls and manufacturing information required by the QS regulation. This information should be included in standard PMA's, modular PMA's, streamlined PMA's, and PMA supplements. Without this information, the premarket review process for these devices cannot be completed (emphasis added)[1].

The law pertaining to PMAs and to PDPs, and the regulations relating to the content of information required to be in PMA applications specifically do not reference any provisions related to design control. In fact, many of the requirements in the Draft Guidance requiring manufacturers to maintain documents at their manufacturing facilities go beyond those specifically required by the Quality System regulation.

II. Many of the "Requirements" in the Draft Guidance Exceed the Secretary of Health and Human Service's Authority Under the FD&C Act

The sections of the FD&C Act that expressly list the requirements for PMAs and PDPs do not include design control. Section 515(c)(1) of the FD&C Act, which discusses the statutory mandated information pertaining to methods and controls related to the manufacture, processing and installation of the device that is required in a PMA, states:

> Any person may file with the Secretary an application for premarket approval... Such application for a device shall contain... (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of the device... [2]

Section 515(f)(3)(B), which discusses the statutory mandated information pertaining to methods

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[1] This statement contradicts the Draft Guidance's footnote number 1 on page 3, which states:

> This document is intended to provide guidance. It represents the agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

[2] Section 515(d)(2)(C) of the FD&C Act tracks the language of section 515(c)(1)(C) for the criteria for denying the approval of a PMA.

and controls related to the manufacture, processing and installation of the device that is required in a PDP, states:

> The Secretary determines that the proposed protocol provides-
> ...(iv) a description of the methods to be used in, and the facilitates and controls to be used for, the manufacture, processing, and when relevant, packing and installation of the device...

The language cited above does not provide the authority for the Secretary to request general information on pre-production design validation in PMAs or PDPs. In fact, the Secretary did not have the authority to require that firms develop pre-production design validation until the passage of the Safe Medical Devices Act of 1990.

Section 520(f) of the FD&C Act provides:

> (1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of the device), ... conform to current good manufacturing practice as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this Act (emphasis added).

The underlined section referred to above contains the language added by the Safe Medical Devices of 1990. The fact that Congress allowed FDA to prescribe regulations for pre-production design validation in section 520(f)(1)(A), and did not modify the relevant sections of the statute pertaining to the information that was to be included in PMAs and PDPs, reinforces the view that PMAs and PDPs were not intended to include an evaluation of the applicant's pre-production design validation process. The relevant sections of the statute referred to above include sections 515(c)(1)(C) and 515(d)(2)(C) relating to PMAs and section 515(f)(3)(B)(iv) relating to PDPs.

Additionally, when Congress added the language in the Safe Medical Devices Act of 1990 allowing the Secretary to prescribe regulations for pre-production design validation, it specifically limited the Secretary's authority. The Secretary was prohibited from promulgating regulations on pre-production design validation that would permit an evaluation of a device's safety and effectiveness. Because the purpose of the review of a PMA and PDP is to determine a device's safety and effectiveness, forcing design validation into the PMA/PDP process is directly contrary to Congress's intent. Moreover, requiring manufacturers to include information on their pre-production design validation procedures in their PMAs and PDPs adds a large amount of additional documentation that fails to serve a useful purpose.

III. Many of the Provisions of the Draft Guidance Exceed or Misinterpret the Quality System Regulation Requirements for Design Control

Even if FDA believes that procedures relating to design control are necessary for the review of PMAs, PDPs, or 510(k)s, many of the requirements described in the Draft Guidance have no counterpart in the law or regulations addressing design control. The FD&C Act makes it clear that the requirements for pre-production design validation are to be prescribed by regulation. No mention is made of providing substantive requirements through guidance. Specifically, section 520(f)(1)(A) of the FD&C Act states:

> The Secretary may, in accordance with subparagraph (B), prescribe regulations, requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety and effectiveness of a device) ...conform to current good manufacturing practice, as prescribed in such regulations... (emphasis added)

FDA, pursuant to section 520(f)(1)(A) of the FD&C Act has through notice and comment rulemaking, promulgated specific requirements that companies need to adhere to for design control under the Quality System regulation. The information required in the Draft Guidance exceeds or misinterprets those requirements. The first sentence in the "Introduction" on page 3 of the Draft Guidance states, "This document discusses information required by the Quality System (QS) regulation..." The requirement for such information is further cited in the italicized section on page 4, which states:

> The following information required under the QS regulation should be submitted with PMA and PDP submissions and readily available, when requested by FDA, for a device subject to 510(k) requirements.

These statements referred to above are misleading. Many of the provisions in the Draft Guidance are not specific requirements in the Quality System regulation. The precise information that the Draft Guidance states needs to be in design control procedures appears to be a variation on the questions that investigators were directed to ask when they evaluated companies using the Final Design Control Report Guidance (here after referred to as "FDCRG"). Although many of the items discussed below are good design and business practices for implementing a quality system, many of these items are not specifically required by the Quality System regulation.

Section 820.5 of the Quality System regulation provides:

> Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, that meets the requirement of this part.

In light of section 820.5, investigators, during an FDA inspection, would not be justified in citing the failure to have all of this information as deviations from the Quality System regulation on Form FDA 483 observations. In fact, Footnote 2 on page 2 the FDCRG provides support for this when it states:

> A negative response to a ... question is not necessarily a citable deficiency.

Firms are only required to have procedures that fulfill the requirements of the Quality System regulation. Since firms are not specifically required to have all of the information in their procedures asked for in the FDCRG, it is highly inappropriate for FDA to require all of the procedures in the Draft Guidance to be submitted in PMAs and PDPs and available when requested by FDA for a device subject to 510(k) requirements. Indeed, this approach appears to elevate the Draft Guidance into an illegal de facto regulation.

Examples of provisions that appear in the Draft Guidance that do not specifically appear in the Quality System regulation include:

820.30 (a)

Item 1 exceeds the requirements in 820.30(a) in that there is no specific requirement to provide an explanation of when design controls apply.

Item 2 exceeds the requirements in 820.30(a) in that there is no specific requirement to provide a description of how risk management or risk analysis will be used throughout the design and development of the device.

820.30 (b)

Item 3 exceeds the requirements in 820.30(b) in that there is no specific requirement for the design and development plan to include information on the development strategy (e.g. Gantt Chart) or to outline the timing strategy, deliverables and milestones that must be completed before the initiation of certain tasks.

820.30(c)

Item 4 exceeds the requirements in 820.30(c) in that there is no specific requirement to include a copy of the written procedure for the identification and control of design input addressing intended use, user/patient/clinical (interfaces and inputs), performance characteristics, safety characteristics, limits and tolerances for safety and performance parameters, risk analysis, toxicity and bio-compatibility, electromagnetic compatibility, compatibility with

accessories/auxiliary devices, compatibility with the environment of intended use, human factors, physical/chemical characteristics, labeling/packaging, reliability, statutory and regulatory requirements, voluntary standards, manufacturing processes, sterility, MDRs/complaints/failures and other historical data, past design history files (DHFs), year 2000 problems for computerized devices and computerized interfaces.

Item 5 exceeds the requirements in 820.30(c) in that there is no specific requirement to provide a summary of how user interface and other human factors issues are considered and addressed in the design input.

Item 6 exceeds the requirements in 820.30(c) in that there is no specific requirement to provide for electronically powered devices an explanation of how EMC issues are considered and addressed in the design inputs.

820.30(f)

Item 9 second bullet exceeds the requirements in 820.30(f) in that there is no specific requirement for a procedure to contain or make reference to a process for resolving any discrepancy between design output and design input requirements. This is a requirement of design input not design verification.

820.30(g)

Item 15 exceeds the requirements in 820.30(g) in that there is no specific requirement for a summary of the risk management program that describes how and when risk management was and will be performed including how the results of the risk management process will be documented, used, and updated.

820.30(j)

Item 19 first bullet exceeds the requirements in 820.30(j) in that there is no specific requirement that if more than one device shares a common DHF, there should be a procedure that describes how the manufacturer identifies each device within the family or group having common characteristics.

Design Control Dossier and Manufacturing Dossier

The guidance document's directive that a Design Control Dossier, a Manufacturing Dossier or a quality manual or other documentation should be consistent with ISO 10013-1195 exceeds the requirements of the Quality System regulation. The requirements of ISO 10013-1195 do not have any legal significance in the United States. If FDA wants these to be legal requirements, it should proceed to include these requirements through notice and comment rulemaking.

IV. Implementing the Draft Guidance as Currently Written Will Divert FDA's Limited Resources Away from Statutory Mandated Activities

FDA officials in public statements have said that FDA's funds are limited and the agency needs more resources if it is to fulfill all of its statutory mandated activities. Having both officials in the Center for Devices and Radiological Health and in the field review a company's general design control procedures for each PMA, modular PMA, streamlined PMA, PMA supplement and PDP is a duplication of effort and is contrary to the scheme envisioned by Congress (discussed in Section II of this document) and the scheme originally envisioned by FDA discussed below.

FDA's Regulatory Scheme

When FDA promulgated the Quality System regulation, it recognized that Congress did not want the agency use pre-production design validation to assess the safety and effectiveness of a device in premarket applications. FDA's regulatory approach was that manufacturers would have a procedure for pre-production design validation (design control) that would contain a process to assess the performance of a device. FDA investigators would evaluate the manufacturer's design control procedures during PMA preapproval inspections. FDA's response to comment 65 to the preamble to the Quality System regulation states:

> FDA will evaluate the adequacy of manufacturers' compliance with design control requirements in routine GMP inspections, including preapproval inspections for premarket approval applications (PMAs) (emphasis added).

FDA's original regulatory plan provided that if, during an inspection, an FDA investigator believed that a distributed device was unsafe or ineffective, the investigator was to send the information to the Center for Devices and Radiological Health. Then, and only under those circumstances, would Center officials take the time to determine if the distributed device lacked safety or effectiveness, and if it was necessary for FDA to take a possible remedial action.

FDA's response to comment 62 of the preamble to the Quality System regulation states:

> ... FDA investigators will evaluate the process, the methods, and the procedures that a manufacturer has established to implement the requirements for design controls. If, based on any information gathered during an inspection, an investigator believes that distributed devices are unsafe or ineffective, the investigator has an obligation to report the observations to the Center for Devices and Radiological Health (emphasis added).

It is redundant, and goes against FDA's original regulatory plan, for officials in the Center for Devices and Radiological Health to check the procedures that a manufacturer has established for design controls when FDA investigators are charged with evaluating this information during

FDA inspections. If the FDA lacks resources, the agency should not have personnel in different offices perform the same function.

The FDA is continually trying to increase efficiency and decrease review times. It is likely that if multiple FDA officials examine numerous design control procedures, review times will increase rather than decrease.

Conclusion

The Draft Guidance is inappropriate in that violates FDA's Good Guidance Practices, exceeds the authority provided to the Secretary in the FD&C Act, does not appear to further the purpose of PMA, PDP, or 510(k) review, and diverts resources away from FDA statutory mandated activities. HIMA requests that the Draft Guidance in its present form not be finalized. HIMA further requests that FDA provide industry with the opportunity to work with the agency in a cooperative effort to achieve a mutually acceptable and appropriate regulatory scheme.

Respectfully submitted,

Nancy Singer

Nancy Singer
Special Counsel