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September 21, 2001

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

RE: Medical Devices; A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Draft Guidance for Industry and FDA Staff [Docket 01D-0281]

Dear Sir or Madam:

Abbott Laboratories submits the following comments in response to the Agency's request for comments on the draft guidance documents "A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures" and "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)" published in the Federal Register on July 25, 2001 at 66 FR 38714.

We appreciate the opportunity to evaluate a harmonized approach to device product submissions. To increase industry participation in the proposed pilot program we suggest the members of the Global Harmonization Task Force (GHTF) coordinate the execution of their pilot programs by including the same device categories and conducting the pilot programs simultaneously. As currently proposed, it appears that each of the four regions, Australia, Canada, European Union, and United States, is conducting its pilot independently of the other regions. Such an approach makes it difficult for device firms to use and evaluate the proposed harmonized submission procedure. Furthermore, we suggest including information about the pilot programs on the GHTF web site. It is extremely difficult to locate the details of each region's pilot program. By incorporating all the information in one location, it will make it easier for device firms to participate in the pilot.

In regards to the content of the Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED), we are concerned that the content differs significantly from that of current FDA regulations for premarket applications, and that such differences will lead to an increase in the amount and types of information provided in premarket applications. Not only is increasing the amount and types of information in premarket applications inconsistent with FDA's Least Burdensome Concept, it also has the strong potential to increase premarket application review times. To address this concern we suggest FDA require, in a global harmonized submission, only those

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sections of the STED that are consistent with FDA regulatory requirements of premarket applications. Comments specific to each of the two draft guidance documents follow.

Comments Specific To "A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures" (Pilot Program Document):

1. Table two indicates that under the FDA pilot program firms would be expected to include, in the STED, each of the cited draft STED sections. Section 7.1.2 of the draft STED references each of the essential principles of safety and performance. Please clarify which of the essential principles of safety and performance FDA would expect in a STED submitted in place of a 510(k) application. In addition, please clarify whether it is FDA's intent for firms to submit STEDs, in place of 510(k)s under the pilot program, in the tabular format included in Appendix B, and whether submission of the table is sufficient or would FDA expect firms to submit supporting data in addition to the tabular STED.
2. Table two refers to section 7.3.1 of the draft STED as a link to performance standards. As this section describes summaries of design verification and validation data (e.g., laboratory tests, software validation) it appears that section 7.3.1 is more appropriately linked to supporting data (21 CFR 807.87(g)). We suggest modifying the table accordingly.
3. Table two references section 7.5 of the draft STED, which is the product risk analysis. Typically, a risk analysis is not included in a 510(k) application. We are concerned with increasing the information currently required in 510(k) applications, and do not believe global harmonization should lead to an increase in submission content. This is a disincentive for participating in the pilot program, and may increase review time periods.
4. On page five, there is a note, which states "[s]ection 7.6 of the GHTF draft STED document, which addresses manufacturing information, is ordinarily not required for a 510(k) submission. " As it is not typical to submit such information and the section is not listed in table two, it appears that FDA does not expect to receive such information under the pilot program. We suggest clarifying this item in the Pilot Program Document.
5. Table three located on page six of the Pilot Program Document refers to section 7.5 of the draft STED, which is the product risk analysis. Typically, a risk analysis is not included in a PMA application. We are concerned with increasing the information currently required in PMA applications, and do not believe global harmonization should lead to an increase in submission content. This is a disincentive for participating in the pilot program, and may increase review time periods.
6. Table three indicates that under the FDA pilot program one would be expected to include, in the STED, each of the cited draft STED sections. Section 7.1.2 of the draft STED references each of the essential principles of safety and performance. Please clarify which of the essential principles of safety and performance FDA would expect in a STED submitted in place of a PMA appliction. In addition, please clarify whether it is FDA's intent for firms to submit STEDs, in place of PMAs under the pilot program, in the tabular format included in Appendix B, and whether submission of the table is sufficient or would FDA expect firms to submit supporting data in addition to the STED.

Comments Specific To "Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)" (STED Document):

1. Without knowing which essential principles of safety and performance apply to each device category, it is difficult to evaluate whether or not the information required in the STED is appropriate. We suggest the GHTF include within the STED Document a link between device class and STED elements, including applicable principles of safety and performance (Section 7.1).
2. We suggest changing the title of section 7.3 from "Summary of Design Verification and Validation Documents" to "Summary of Design Verification and Validation Data." The title implies that this section is to include a firm's design verification and validation standard operating procedures. However, the description is focused on design data.
3. Sections 7.5 and section 7.1, via essential principle two, of the STED require a risk analysis. Currently this information is not provided in FDA premarket applications. We are concerned with increasing the information currently required in premarket applications, and do not believe global harmonization should lead to an increase in submission content. Additionally, an increase in submission information may increase review time periods.
4. Sections 7.6 and 7.1, via several essential principles, of the STED require manufacturing information. This information is not required in 510(k) submissions. We are concerned with increasing the information currently required in 510(k) applications, and do not believe global harmonization should lead to an increase in submission content. Additionally, an increase in submission information may increase review time periods.

Thank you for the opportunity to provide these comments. Should you have any questions, please contact April Veoukas at (847) 937-8197 or by facsimile at (847) 938-3106.

Sincerely,

for:

Douglas L. Sporn
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