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July 18, 2001

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

RE: Docket No. 015-0202 – Draft "The Least Burdensome Provisions of the FDA Modernization Act of 1997"

To Whom It May Concern:

Attached please find comments regarding the above reference docket regarding comments to the Draft "The Least Burdensome Provisions of the FDA Modernization Act of 1997.

Sincerely

Sandi Hartka
Manager Regulatory Affairs

REF: SH01-107

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Comment to FDA Least Burdensome Guidance
Docket No. 01D-0202

1. RE: I. Background

Reference is made to several examples of situations in which the Agency has utilized a least burdensome approach to bring a new device to market. We applaud FDA's approaches in these situations. We would like to see further application of these principles in other review branches. We understand that it takes some education and time for implementation of principles such as this. We recommend that training and follow up activities be used to reinforce the type of practices mentioned in this guidance document. One recommendation for follow up may be to survey sponsors whose submissions have been cleared/approved to obtain their agreement or concerns regarding whether least burdensome was applied to their specific submission. With this information the Agency may be able to focus training/education to areas that require review and possibly changes.

2. RE: V. How do the Least Burdensome Principles Apply to 510(k)'s?

Reference is made that FDA should not request information regarding changes observed in a new 510k that were previously implemented by industry without the requirement for 510k clearance unless the lack of information regarding the previous modifications does not allow the SE determination to be made. We strongly agree with this statement. We have been requested to submit performance data supporting changes (not requiring a 510k submission) in a current 510k for the further modified device. Our current submission (for a change requiring a 510k) presented the performance testing (for the device with the old plus new modification) to establish equivalence, i.e., the current performance data demonstrated equivalence of the device with the old plus new modifications. However, the Agency still requested to review the performance data for the old modification alone. We think this is not an application of the least burdensome principles that further indicates the need for training over all review groups to assure a consistent understanding of the least burdensome principles.

Additionally, manufacturers should not be required to submit data nor should FDA request data for a device that meets an FDA recognized standard when acceptance criteria are established.

Manufacturers should be encouraged to include variations of a device in a single 510k submission. Such variations include lengths, sizes, color, etc. Performance data should only be required for the device representing worst case.

Reference is made that summary information re performance testing should be sufficient. We strongly agree with this statement, however, recent experience has

been to the contrary. We urge appropriate training across all reviewing divisions to reinforce implementation of this concept.

3. RE: VI. What are Some General Applications…..

This section mentions that industry should incorporate by reference other premarket submissions, whenever possible and FDA should encourage and accept this practice as a means of savings resources. We strongly agree with this concept. We have tried this approach very recently and have been instructed by the reviewer to submit the data and not reference other submissions. This means that FDA has reviewed the same packet of data at least four times. Our reaction to the continued submission of the same packet of safety data is that industry resources and FDA resources are not being appropriately utilized. We recommend that the Agency clarify in this guidance document circumstances that will require re-submission and circumstances that will not require re-submission of previously reviewed data/information so that both industry and FDA will have clearer guidance regarding this issue.

Use of 3rd party peer reviewed journal articles to support device claims re performance, safety and effectiveness should be permitted. This guidance document should reflect the Agency's position on use of 3rd party peer reviewed articles and any restrictions or requirements that need to be met in order to successfully use this type of information.

Recommend addition of the bolded clarifying information:

> "Industry should incorporate by reference other premarket submissions **(IDE, 510k's, PMA),** whenever possible."

Recommend indicating that testing of well-characterized materials may be avoided by a review of the current literature. Use of this supporting information will reduce unnecessary testing and use of animals.

This section indicates when requesting additional information to resolve a regulatory issue, FDA should:…..Establish the relevance of the request to the determination that is being made, i.e., substantial equivalence or reasonable assurance of safety and effectiveness…..

> If industry receives a letter from FDA requesting additional information and the only 'reason' indicated is 'to establish substantial equivalence', this does not assist industry in determining the underlying concern of FDA. Obviously all the information submitted in the 510k is 'to establish substantial equivalence' and most submitters present the data that is thought sufficient to make this decision. When FDA requires some additional information, it would assist the submitter to understand exactly why the additional information is being requested. In other words, it would help industry

adequately address FDA's concern if an explanation of the reason, for example, of why testing of some particular attribute is necessary. This is a benefit not only for the current 510k but also for future submissions. We recommend this guidance reflect the necessity for reviewers to clearly explain the rationale for requiring the new information instead of simply indicating it is needed 'to establish substantial equivalence' since this phrase does not reveal the underlying intent of the request.

4. RE: Hyperlink #12

Recommend clarifying that the sterilization method validation data should not be provided in the 510k.

5. RE: Hyperlink #14

This section mentions reclassification as a tool industry should pursue when appropriate. Our company has participated in several reclassification attempts within the last few years. These petitions have been submitted for several years. Recently three of them have been reclassified, however, one petition (the first petition submitted) has been under review by the agency for over 6 years. As of today, there is no indication as to whether or not the reclassification will occur. As a result of these experiences, the reclassification tool does not seem to be a reasonable approach for a timely decision to ensure that the proper level of regulatory control is applied to a device type. We recommend the Agency provide some clarification or guidance that will enhance the ability to achieve timely reclassifications and thus render this a realistic tool.

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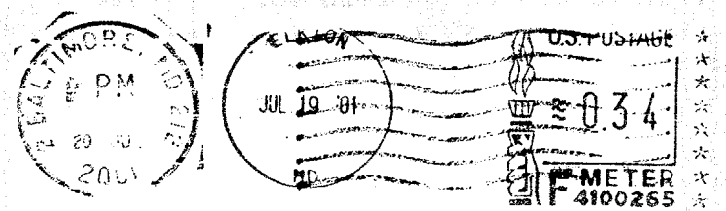

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