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30 August 2000

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
(HFA-305)
Room 1061
Rockville
MD 20852
United States of America

Dear Sir or Madam:

Docket No: 98N-0331: Extension of FDA Third Party Programs Under the FDA Modernization Act of 1997 – June 2000 – Draft Guidance

The British Standards Institution (BSI) is one of the world's premier standards development, testing, inspection, training and certification organizations. It is a Notified Body for a number of EU Directives and in particular the Medical Devices, Active Implantable and IVD Directives. It's US-based sister-company, BSI America, Inc. supports BSI's Notified Body activities and is actively seeking CAB status in the USA and Canadian Medical Devices Conformity Assessment Scheme (CMDCAS) approval in Canada.

BSI welcomes and strongly supports this proposed initiative to broaden the number of devices eligible for 510(k) third party review covered by the Third Party Program under the FDA Modernization Act of 1997. There are, however, a number of issues where we believe it might be appropriate to reconsider the proposals within the draft that will strengthen and improve the proposed guidance document. Within the spirit of openness and developing cooperation between the FDA, industry and third parties our comments on these issues are as follows:

The extension of the program to include third party reviews of 510(k) where there is no existing device-specific review guidance is welcomed as a progressive initiative. On the one hand, it seems reasonable that before a third party may undertake the review of a 510(k) for a device, with no device-specific review guidance, that the third party must have demonstrated its review capability by having satisfactory completed 510(k) reviews of a predetermined number of regular reviews. The number of reviews proposed by FDA of 3 may seem appropriate. On the other hand one has to question why this requirement is necessary for those Accredited Persons that have

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already been evaluated by the FDA. We respectfully request the FDA to give serious consideration to eliminating this requirement and retaining the criteria FDA has already established and used for qualification. It is assumed in this context the Accredited Person is taken to be in its widest context i.e. the entire third party organization and not individuals within the third party.

We are concerned about the requirement that at least one of these reviews must be a device that is the 'same or similar medical specialty area as the device the Accredited Person now intends to review'. In our opinion this requirement will severely restrict the benefit of the proposed extension of the program. A perception would be created that the program has been extended, but this requirement will in practice negate the benefit of this extension. We would suggest that where an Accredited Person has been identified as competent to review in a particular product area then this should be sufficient. Where the device has no device-specific review guidance, the requirement for pre-review discussions with ODE should ensure that the third party is proposing an appropriate methodology for the review.

Regarding the pre-review discussion we suggest that in order to ensure efficiency of the review ODE should make available to the third party any relevant 'review memos' or internal 'checklists' that might currently exist within ODE. It is essential for the success of program that the third parties have ready access to all available current information, accumulated by ODE. By providing access to this information ODE will be demonstrating significant support to the third party program and ensuring that the efforts of all parties are targeted on achieving the most effective and timely reviews. It is suggested that one of the outputs of the pre-review discussions is a checklist that documents agreement between the ODE and the third party on the proposed review. It is suggested that ODE maintains copies of these decisions and checklists, these documents should also be made available to other third parties when relevant to reviews that they may be conducting. As the database of decisions and related information accumulates it makes sense that all involved parties are able to review and benefit from previous experience gained. We encourage the FDA to view the Accredited Person as simply an extension of the FDA and hence make all relevant information openly and readily available.

The program should also address the need for ongoing training of Accredited Persons, whilst it is recognized that the training provided by FDA is very good and relevant it is restrictive on the development reviewers and dependent on when FDA determines there is need. It is suggested that FDA in cooperation with the third parties and industry develop a specification for training requirements that could be provided by third party trainers (e.g. consultants). This would allow the Accredited Persons more flexibility in getting staff approved for use for 510(k) review, whilst still maintaining a high level of consistency. It should also help to increase the pool of trained expertise. We need to seek innovative ways to develop, implement and maintain adequate training programs that meets the needs of all stakeholders. This cooperative approach has had significant success in other third party schemes in both regulated and non-regulated industries.

Sensitivity to conflict of interest is well understood and respected amongst third party bodies and is thoroughly covered by existing standards and other requirements documents. One of the benefits of the third party model is the investment made by the third parties and the manufacturers in developing reviewers to have a thorough and detailed knowledge of devices and the associated issues. This investment will be wasted and lost if reviewers are not permitted to develop ongoing involvement with products and manufacturers. The question of integrity is essential, but it can be appropriately addressed by the third parties without unnecessary conflict of interest restrictions, restrictions that may be counter productive to ensuring review by the best available expertise.

To truly measure the success of this program will require a number of initiatives to be implemented (e.g. education, training, marketing and promotion etc.) that will take a significant amount of time. Consequently we suggest an extension of the proposed 12-month timeframe to 24 or 36 months with agreed criteria set to measure, monitor and regularly report on the success of the program over this period.

The FDA should also consider the establishment of an Accredited Person meeting forum where, FDA and Accredited Persons can meet and discuss issues of interpretation and guidance and reach mutually acceptable solutions. As an example within the UK the Medical Devices Agency (MDA) has an established a tripartite forum for UK third parties which has greatly assisted UK third parties to exchange experience with representatives from the MDA. The third parties meet firstly in private, then are joined by the MDA, and later by industry representatives, this forum has proved invaluable in developing the UK third party model. Significant efficiencies can be realized by pooling resources and working together towards mutually agreed goals.

To assure success of the Accredited Persons review program requires an environment of cooperation and partnership between the FDA and the Third Parties, there needs to be respect between both partners and mutual support to ensure the objectives of the regulators and the industry are satisfied. This can only be successfully achieved by working in close cooperation.

BSI offers these comments in its capacity as an Accredited Person committed to supporting the FDA's initiatives to involve third parties and to achieve confidence in the program that results in effective and reliable reviews.

Yours sincerely


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and


Reg Blake
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