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Indispensable to human health

August 10, 2001

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

RE: Docket No. 01D-0202; FDA Draft Guidance Document titled "The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Draft Guidance for FDA and Industry"

Dear Sir or Madam:

These comments are submitted by Becton Dickinson and Company (BD) in response to the Food and Drug Administration's (FDA's) draft guidance entitled "The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Draft Guidance for FDA and Industry". BD is a multi-national corporation that manufactures and sells a broad range of medical supplies, devices and diagnostic systems. The company serves health care professionals, medical research institutions, industry, and the general public.

BD appreciates the opportunity to provide comments on this document.

General Comments

BD believes that the following represent significant and positive improvements in the regulatory process:

- Explicitly stating that the least burdensome concept applies to *in vitro* diagnostics (IVDs). IVDs are a subset of medical devices that, while different in many respects from other medical devices, we do not believe Congress intended to exclude them from the least burdensome provision of FDAMA.

- Applying the least burdensome concept and principles to premarket and postmarket regulatory activities, including presubmission inquiries and meetings, premarket submissions, reclassification petitions, and guidance document development. We recommend that agreement and determination meetings be clearly specified in the bullet-point list of activities in Section II.

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- Stating that reviewers should not request information on modifications that do not require a 510(k) unless the lack of that information does not allow a substantial equivalence determination for the device under review. This issue has been problematic and has resulted in submission of data that were not relevant to the SE decision.

- Recognition and promotion of the use of standards as an avenue to streamline the regulatory process. The use of FDA-recognized standards and the process for future recognition of additional international standards provides both the industry and the FDA with a useful and valuable tool to meet the challenging requirements of a global market.

- The format of the draft guidance document is user friendly and the use of the "Hyperlink" feature provides a suitable method to expand and discuss specific topics within the document that may have required further information and/or explanation. This type of format could be used in future guidance documents to aid in clarification of terminology and expansion of subject matter within the guidance.

In addition to the foregoing, BD has identified several clarifications and revisions. These are enumerated below:

The terms "analytical testing" and "clinical data" should be defined in this document. Section V has a statement that performance testing should be submitted if there are important descriptive differences between the new device and other devices of the same type, and that for IVDs, "analytical testing" should be provided. Does this mean testing to define what are usually called the analytical performance characteristics of the IVD (e.g., precision, limit of detection, cross-reactivity, effects of interfering substances)? Or does the term "analytical testing" include testing of clinical specimens from defined populations to establish what are often called the clinical performance characteristics of an IVD (clinical sensitivity and specificity)? The document goes on to indicate that "clinical data" are not required for most 510(k)s and that the FDA should document the issue that warrants the inclusion of clinical data in a 510(k). One could assume that the term "analytical testing" includes all testing to establish the performance characteristics of an IVD and that "clinical data" refers to results and information gathered from procedures and assessments performed on human subjects (not specimens from human subjects). Clear definitions that are used consistently within both FDA and industry would help tremendously in understanding how FDA policies apply to IVDs.

In Section V, the last paragraph states: "Manufacturing information should not be part of a 510(k) submission unless the information relates to the equivalency determination." We would recommend that the statement include a reference to "Quality Control" information as well as manufacturing information. The statement should read:" Manufacturing and quality control information..." We agree with the explanation provided in Hyperlink #12 and strongly support the FDA intentions to focus the submission review on substantial equivalence determinations instead of manufacturing issues.

In Section VI, the inclusion of the other methods to resolve minor questions/deficiencies (phone fax, e-mail) is a positive action and has been used in the past with very good success. We would recommend that these types of communications be recognized as part of the official record for

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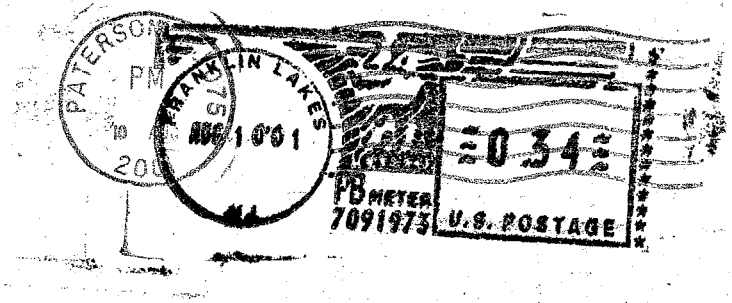

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