MDMA MEDICAL DEVICE MANUFACTURERS ASSOCIATION

Serving the Innovator and Entrepreneur in the Medical Device Industry

June 20, 2001

Dockets Management Branch (HFA-305)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 01D-0202: The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Draft Guidance for FDA and Industry

Dear Sir or Madam:

The Medical Device Manufacturers Association (MDMA), which represents the entrepreneurial sector of the medical device industry, recommends that the Food and Drug Administration (FDA) accelerate its finalization of "The Least Burdensome Provisions of the FDA Modernization Act of 1997; Concept and Principles; Draft Guidance for FDA and Industry." We believe the concepts elucidated in this draft guidance document adhere substantially to the letter and the spirit of the Food and Drug Administration Act of 1997 (FDAMA), and we write this letter to encourage the agency to expedite the training of its reviewers on how to incorporate these concepts in their work.

We believe there has already been much significant interaction between the industry and the FDA in the development of this draft guidance, and we therefore anticipate that any additional comments on the draft guidance will not require major revisions to the document. Therefore, we would like to see the FDA begin using this draft guidance as if it were a final document. We further request, though, that any additional comments on this draft guidance be considered fully.

In addition, we note that, as part of its February 28 final guidance on the "early collaboration meetings" required under Sections 201 and 205 of FDAMA, CDRH published a set of checklists that it will collect from meeting participants. According to the guidance, the FDA intends these checklists for use by both the applicant and the agency's review team leader in assessing the FDA's incorporation of the "least burdensome" approach in determining the type of valid scientific evidence needed for marketing approval.

MDMA believes that the FDA should use such checklists or other appropriate tools as part of an ongoing process of measuring the application of the "least burdensome" principles in the day-to-day work of the agency. Without such evaluation, it will be impossible to determine whether the "least burdensome" provisions of FDAMA are being implemented successfully or whether controversies that arise between the agency and manufacturers are isolated difficulties or represent more systemic problems.

Very sincerely yours,

Stephen J. Northrup
Executive Director

01D-0202

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