DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

December 22, 1997

Dear Manufacturer:

The Center for Devices and Radiological Health (CDRH) would like to announce a pilot program for review of PMA submissions by the Division of Clinical Laboratory Devices (DCLD).

The purpose of this pilot is to streamline our PMA review process. The intent is to allow more timely reviews of certain original PMA submissions in DCLD. This pilot will begin January 1, 1998.

We hope to accomplish this reduced review through pre-submission interactions assisting the companies in submitting documents that are ready for review, and by streamlining the administrative process.

Ideal candidates for this pilot would include any of the following:

a. devices where a review guidance exists, or

b. submissions for which two or more previous PMAs have been approved, or

c. study protocols jointly developed with FDA

Because a pre-agreed study protocol is critical to this pilot, the program may not be abale to accomodate investigational studies already underway for class III devices.

Although this pilot is targeted at devices utilizing well known technologies with well known disease processes, the division is interested in ultimately expanding this review effort to include a broader array of devices.

How to participate in the Streamlined PMA pilot:

a. Contact Dr. Joseph Hackett by phone at 301-594-3084, or fax at 301-594-5940 to schedule a teleconference or a meeting. At the scheduled interaction it will be determined how best to proceed.

b. Determine if a review guidance or 2 previously approved PMAs exist for similar devices.

c. Jointly establish a study protocol with FDA.

To assist in making this effort a success, FDA welcomes input from individual companies, groups of companies, or trade associations to help establish generic protocols or evaluative approaches or templates which can be used to help simplify and standardize data sets for review. The division is also interested in testing a wide variety of procedure changes intended to make the review process more friendly for both sponsors and agency scientists. At the request of interested parties we would be pleased to work with you in the development of good scientific models for both old and relatively new PMA devices either in the form of panel meetings, cooperative workshops, or other interactive scientific venues. Parties with an interest in initiating or participating in such a trial effort are asked to call or write to appropriate management in the division.

The division anticipates mutual benefit in terms of reduced time form receipt to approval of these pilot PMAs. We do not expect the pilot to delay review times for other types of documents.

Comments will be welcomed during the first 6 months of the pilot. These should be addressed to:

Dr. Joseph Hackett
Associate Director
HFZ 440
2098 Gaither Rd.
Rockville, MD 20850

If you have any questions, please contact Dr. Hackett at the above phone number.

Sincerely,

S. Gutman

Steve I. Gutman, M.D., M.B.A.
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