



Medical Products Group

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Division of Dockets Management (HFA -305)
Food and Drug Administration
5630 Fishers Lane - Room 1061
Rockville, MD 20852

RE: *The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations; Draft Guidance for Industry and FDA Staff [Docket 2006D-0063]*

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA draft guidance document "The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations," published in the Federal Register on June 19, 2006 at 71 FR 35275.

Thank you for the opportunity to provide these comments. In general, the document is informative in explaining FDA's processes for reviewing a PMA manufacturing section and conducting a pre-approval inspection.

Specific Comments

Page 1

For clarity and ease of use, include a table of contents with hyperlinks to document sections.

Types of PMA Supplements

Pages 4-5

Subsections B.1. and B.2. (Panel Track Supplements and 180-Day Supplements, respectively) are unnecessary, since they reiterate information contained in an existing guidance document. Also, to avoid potential issues with document management, we recommend referencing the existing guidance document without reprinting sections into

2006D-0063

C1



this document to ensure consistency between the two guidance documents should the existing document undergo revisions.

FDA Review of the PMA Manufacturing Section and the Inspection Process

Page 7 (Item 4)

Line eight of item four contains a typographical error. "OIG" should read "IOG" in ORO/DFI/OIG.

Page 8 (Subsection B.1.)

The guidance limits real time communication to phone. E-mail and fax communications are also used to engage in real time interactions. We recommend updating the guidance document to include e-mail and fax as acceptable forms of real time communication.

Page 8 (Subsection B.2.)

It would be helpful, if manufacturers were aware of the criteria and the decision making process used by OC and OIVD when reviewing the district office's recommendation to determine the need for an inspection. We recommend including a reference to the document that provides the criteria in determining whether a facility requires an inspection.

Page 9 (Subsection B.3.)

In this section and on page eleven, the document states the manufacturing process should be in operation by the time the scheduled inspection is conducted. It is not always feasible for the manufacturing process to be in operation. This should be considered on a case-by-case basis considering the unique circumstances of the manufacturing process, product, etc. Additionally, we recommend considering alternative mechanisms to demonstrate the capability of the manufacturing process.

Page 9 (Subsection B.4.)

Cancellation of inspection assignments should not always follow issuance of a major deficiency letter, but should be evaluated on a case-by-case basis. Prior discussion with the sponsor is recommended, as the sponsor may have the information readily available for submission to the agency. Examples in the guidance of what constitutes a "major deficiency" for purposes of canceling an inspection assignment would be useful.

If a facility is not ready for inspection, the applicant is instructed to send a letter signed by the most responsible person at the firm. We recommend the agency implement a least burdensome approach allowing the use of e-mail and fax as alternatives to a letter and accepting the communication from site quality and regulatory affairs as alternatives to the most responsible person at the firm.

The document states, "[t]he applicant should alert CDRH in advance of when the facility will be ready for inspection." Additional guidance regarding the appropriate process is recommended. The use of real time communication, such as phone, fax, or e-mail, is recommended, as it is the least burdensome process for manufacturers.



Page 9 (Subsection D.)

This section does not address situations in which the facility is found to be in compliance or when minor deficiencies are identified. Furthermore, the communication of minor deficiencies to the sponsor is not discussed. We recommend addressing these situations. In regards to minor deficiencies, we recommend communicating this information to the facility during the inspection close out meeting. Also, for clarity and to improve understanding we recommend reformatting this section into subtopics or bullet points, such as:

- When the manufacturing facility is found to be in compliance FDA...
- When the inspection identifies minor deficiencies FDA...
- When the inspection identifies deviations that are significant and limited to the PMA device FDA...

Should you have any questions, please contact me at (847) 937-8197 or by facsimile at (847) 938-3106.

Sincerely,

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Abbott Laboratories