

October 30, 2003

Dear Panel Member:

Please review the information contained in this binder in preparation for the discussion of Q-Med's Restylane (P020023), at the November 21, 2003 meeting of General and Plastic Surgery Devices Advisory Panel.

This binder includes:

Tab 1 – Q-Med's CD with a hardcopy of the CD's table of contents.

The CD-ROM has been organized to allow you to link to relevant portions of the submission. This information is identical to that information in the PMA. The disk has a table of contents to allow you to see what information is on the disk

Tab 2 FDA Review Memos

This contains copies of the lead review memos, preclinical review memos, clinical review memos and summary statistical review memo.

Tab 3 Draft Labeling and Draft Summary of Safety and Effectiveness Data

Tab 4 Draft Panel Questions

Tab 5 Comprehensive table of contents for the PMA

This table of contents for the PMA and Amendments list both the items on the CD (bolded) and items left off the CD (not bolded). If you would like copies of any information that is not on the disk, please feel free to contact me and we will get it out to you as soon as possible.

I have also provided a brief chronological summary to help you understand the major issues and provide you a context before you delve into the reviews and the data. If you need anything or have any questions, please feel free to call me at (301) 594-3090 x142 or e-mail me at ADW@cdrh.fda.gov. You can also call Dr. David Krause, the Panel Executive Secretary at (301) 594-3090 x141.

Sincerely,

Anthony D. Watson
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Center for Device and Radiological Health
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