

October 31, 2003

Dear Panel Member,

On behalf of the FDA, I want to thank you for agreeing to participate in the November General and Plastic Surgery Devices Panel meeting. The meeting will be held on November 21, 2003 in the Walker/Whetstone Rooms of the Gaithersburg Holiday Inn located at two Montgomery Village Avenue in Gaithersburg, Maryland. The entire meeting will be open to the public and will be in session from approximately 8:00 am until 5:00 pm on November 21, 2003 (there is a possibility that the meeting will last until 6:00 pm). Please be in the Meeting room by 8:00 am as we anticipate a full day of hearings.

This Panel Member Package contains some of the essential material for the Panel review of the premarket approval (PMA) applications for Restylane Injectable Gel (P020023) sponsored by Q-Med AB and Hylaform from Genzyme Biosurgery (P030032). Please see the cover memos for the Restylane and Hylaform panel packs for details on the contents. During the afternoon of November 20th, there will be a general panel training session from 3:00 pm until 6:00 pm in the Seneca Room of the Holiday Inn. Any panel member attending this meeting may attend, however, only panel members who have not been previously trained (Drs. Bartoo and Halsey) are required to attend.

During this committee meeting, the Panel is asked to consider the safety and effectiveness of these devices for their stated uses. The Panel will hear presentations from Q-Med, Genzyme Corporation and from FDA staff. FDA will be including separate questions for Restylane and Hylaform in the Panel Member Packages for discussion at the meeting. Read these carefully and review all of the submitted material with these questions in mind. After the Panel has addressed the questions and any other pertinent issues, it will vote on a recommendation to FDA on each PMA presented. The three possibilities are: approvable, approvable with conditions, or not approvable. The voting procedure will be discussed at the training session. For those of you who have voted before, but feel you need a refresher, you may attend the training session or contact me to review of the voting procedure.

The materials that you receive should be held in the strictest confidence. Please do not share any of this material with others. You may mention that you will be participating in a FDA General and Plastic Surgery Panel meeting on November 21, and that the Panel will be discussing PMAs for injectable soft

tissue augmentation devices. For further information, any interested person may call the FDA Medical Advisory Committee telephone line at 1-800-741-8138, and enter the code 12519, which is the code for the General and Plastic Surgery Panel, a pre-recorded message about the Panel meeting will be heard.

Please bring the mailed materials with you to the Panel meeting for your reference and so that it may be returned to the FDA for proper disposal. If you request further information on the PMA and do not wish to bring it with you to the Panel meeting for disposal, other arrangements can be made for appropriate disposal of the documents. We will have complete copies of the mailed materials at the meeting for your reference. If there is anything I can help you with concerning either the meeting agenda or logistics, please let me know. My phone number is 301-594-3090, extension 141, my fax number is 301-827-4350, and my e-mail address is dxk@cdrh.fda.gov. Should you need to reach me at home, my home telephone number is 410-451-0953. I do work at home one day a week (Thursdays), most weeks, if my schedule permits. I look forward to seeing you all soon and to having a productive meeting. Thank you for your participation on the panel and please travel safely.

Sincerely yours,

David Krause
Executive Secretary
General and Plastic Surgery Devices Panel