



DEPARTMENT OF HEALTH & HUMAN SERVICES

- 8 MAY 2009

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Charles E. Grassley
Ranking Member
Committee on Finance
United States Senate
Washington, D.C. 20510-6200

Dear Senator Grassley:

Thank you for your letter of March 6, 2009, requesting documents and information relating to the review activities of the Food and Drug Administration (FDA or the Agency) for the ReGen Collagen Scaffold, a product sponsored by ReGen Biologics, Inc., and your subsequent letter of April 2, 2009, with Chairman Baucus from the Finance Committee.

You posed several questions:

- about the input product sponsors typically have with respect to advisory committee meetings to review their products;
- about the involvement of the Office of the Commissioner in product reviews and advisory committee meetings generally and with respect to ReGen's Collagen Scaffold, and the November 14, 2008, meeting of the FDA's Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, specifically;
- about whether and how the Agency disclosed to that committee panel the affiliations with ReGen of the authors of an article the panel reviewed; and
- about ReGen's concerns about bias of a member of that committee panel and how the Agency excluded that member from participating in the November 14 panel meeting.

You also requested documentation supporting the decision to exclude that panel member; all documentation related to ReGen and the FDA, the make-up of the advisory committee for the November 14 meeting, and the development of panel questions for that meeting; and an interview with the Agency's review team leader for the product.

Your questions and the controversy surrounding this matter raise legitimate concerns about whether the Agency's review process and decision to clear for marketing the ReGen Collagen Scaffold were compromised. These concerns have prompted me to have

the Agency undertake a preliminary internal review of the review and clearance of the product. This review will address the following issues:

1. Whether established processes and procedures were followed;
2. Whether the integrity of the advisory committee process was compromised;
3. Whether the integrity of the review process was compromised;
4. Whether a separate reconsideration of decision to clear the ReGen Collagen Scaffold for marketing should be undertaken; and
5. Whether changes to any FDA policies, processes, or procedures should be made to protect the integrity of FDA's decision-making.

The FDA's Acting Chief Scientist, Acting Chief Counsel, and Associate Commissioner for Policy and Planning will lead this review, with staffing by a team of scientific, legal, and other appropriate staff who were not directly or indirectly involved in the review or clearance of the ReGen Collagen Scaffold. This team will review documents, interview individuals, and gather other information as it deems appropriate. The team will develop draft findings and recommendations within 12 weeks.

Although we are not able to answer your questions at this time, I expect that this review will develop information relevant to your questions and the legitimate concerns they raise. We look forward to providing you a copy of the findings and recommendations that come out of this review.

Please be assured that, concurrent with this review, the Agency will be responding to your request for documents. The Agency is working on your document request, and you have already interviewed the Agency employee, as requested in the April 2 letter.

Thank you again for your interest in this matter. If I can be of further assistance, please contact me.

Sincerely,



Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner
Acting Commissioner of Food and Drugs