DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Tuesday, October 06, 2015

Public Citizen Health Research Group
Michael Carome, M.D.
Sarah Sorscher, J.D.
1600 20th Street NW
Washington, DC 20009

Re: Citizen Petition – Docket Number FDA-2015-P-2375

Dear Dr. Carome & Ms. Sorsher:

This is an interim response to the petition dated July 7, 2015, filed by the Food and Drug Administration (FDA) on July 7, 2015. In the petition, you requested FDA withdraw approval of Seprafilm Bioresorbable Membrane (Seprafilm), premarket approval application number P950034, and initiate a mandatory recall of this product.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Adaeze Teme of our Regulations Staff at (240) 402-0768.

Sincerely yours,

William H. Maisel, MD, MPH
Deputy Center Director for Science
and Chief Scientist
Center for Devices and Radiological Health
Food and Drug Administration