



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Silver Spring, MD 20993

July 7, 2015

Public Citizen Health Research Group  
Michael Carome  
1600 20<sup>th</sup> Street NW  
Washington, DC 20009

And via email to: [mcarome@citizen.org](mailto:mcarome@citizen.org)

Dear Petitioner,

Your petition to the Food and Drug Administration requesting that the FDA withdraw approval of Seprafilm Bioresorbable Membrane (Seprafilm), premarket approval application number P950034, and initiate a mandatory recall of this product, was received by this office on 07/07/2015.

It was assigned docket number FDA-2015-P-2375, and it was filed on 07/07/2015. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, appearing to read "D Bigby", enclosed in a rectangular box.

Dynna Bigby  
Supervisory Administrative Proceedings Specialist  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)