DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 24, 2014

FILE COPY

Edward John Allera
Buchanan, Ingersoll &Rooney PC
1700 K Street N.W., Suite 300
Washington, D.C. 20006

Dear Mr. Allera:

Your petition to the Food and Drug Administration requesting that FDA reconsider the determination that its product Preopik, may not be granted five-year NCE exclusivity under the new statutory interpretation of the exclusivity provisions being adopted by FDA, was received by this office on 03/21/2014. It was assigned docket number FDA-2013-P-0119, and it was filed on 3/24/2014. 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,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)