



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

July 8, 2019

Steven Giardino  
President and CEO  
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St. Petersburg, FL 33702

Sent via email to: [admin@medicalresearchcollaborative.com](mailto:admin@medicalresearchcollaborative.com)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to have Amarin Corp.'s U.S. Patent No. 8,188,146 (the '146 patent) removed from the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, for being improperly listed, was received by this office on 07/08/2019.

It was assigned docket number FDA-2019-P-3265. 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,

Dynna Bigby  
Supervisory Administrative Proceedings Specialist  
Division of Dockets Management  
FDA/Office of Operations (OO)