



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

January 23, 2017

Paul E. Kalb, Coleen Klasmeier
Joseph R. Guerra, Sean C. Griffin
SIDLEY AUSTIN LLP
1501 K Street NW
Washington, DC 20001 (202) 736-8000

James C. Stansel
PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF
AMERICA
950 F Street NW, Suite 300
Washington, DC 20004

John Murphy
BIOTECHNOLOGY INNOVATION
ORGANIZATION
1201 Maryland Avenue, SW Suite 900
Washington, DC 20024

Kellie B. Combs
Douglas H. Hallward-Driemeier
ROPES & GRAY LLP
2099 Pennsylvania Avenue NW
Washington, DC 20006

Joan McPhee
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, NY 10036

Justin Florence
ROPES & GRAY LLP
800 Boylston Street
Boston, MA 02199

Dear Petitioners:

Your submission requesting that the Commissioner of Food and Drugs take the actions as described in your petition to stay and for reconsideration was received by the Division of Dockets Management on 02/08/2017.

It was associated with the following docket numbers:

FDA-2016-N-1149
FDA-2015-N-2002
FDA-2013-P-1079
FDA-2011-P-0512

The petition was filed on 02/09/2017. Please refer to these docket numbers 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 dark ink, appearing to read 'DBigby', with a stylized, cursive script.

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