DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

December 10, 2019

Anthony T. Pierce
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2001 K Street NW
Washington, DC 20006

Sent via email to: apierce@akingump.com.

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA:

(1) refrain from clearing, approving, recommending, or issuing a "safety measure" designation for Large Volume Delayed Sampling ("LVDS") as a single step bacterial culture technology for dating beyond Day 5 without first obtaining statistically conclusive data supporting the safety and effectiveness from clinical evidence on apheresis platelets demonstrating that the LVDS method is effective at preventing the transfusion of bacterially contaminated blood platelets beyond Day 5;

(2) refrain from clearing, approving, recommending, or issuing a "safety measure" designation for any other platelet contamination detection method, storage device or method, or pathogen reduction method without statistically conclusive data supporting the safety and effectiveness from clinical evidence on apheresis platelets demonstrating that the technology or methodology is effective at preventing the transfusion of bacterially contaminated blood platelets; and

(3) refrain from clearing, approving, recommending, or designating as a "safety measure" any technologies or methodologies without statistically conclusive data supporting the safety and effectiveness of the technologies or methodologies.

Your submission was received by this office on 12/06/2019, and it was assigned docket number FDA-2019-P-5800. 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 -S
Digitally signed by Karen Kennard -S
Date: 2019.12.10 15:58:56 -05'00'

Karen Kennard
Director
Dockets Management Staff
FDA/Office of Operations (OO)

CC: Daniel D. Graver - dgraver@akingump.com