Monday, February 17, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2013-D-1358 – **Draft Guidance for Industry: Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen (HLA) Test Kits Used for Transfusion and Transplantation**

To Whom It May Concern:

On behalf of the American Society of Transplantation (AST), representing the majority of professionals engaged in the field of organ transplantation, I write to you in full support of the attached comments from the American Society for Histocompatibility and Immunogenetics (ASHI) regarding the Food and Drug Administration's (FDA) recent draft guidance for industry Docket No. FDA-2013-D-1358.

AST is concerned that the FDA's recent draft guidance (as currently drafted and proposed) will significantly delay the use of newly available HLA allele information in transplant decision making. AST joins ASHI in requesting that the FDA amend the draft guidance to ensure that patient care is not negatively impacted by what appears to be unintended consequences of the proposal as currently drafted.

Thank you in advance for your consideration of our request. If you have any questions, please do not hesitate to contact me directly.

Best Regards,

Daniel Salomon, MD
President, American Society of Transplantation

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