DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

July 25, 2017

Yolanda Giraldo, M.D. M.P.H
Resident, General Preventive Medicine
John Hopkins School of Public Health

Sidney Wolfe, M.D.
Founder and Senior Advisor
Public Citizen's Health Research Group

Charles Natanson, M.D.
Critical Care Physician

Sammy Almashat, M.D., M.P.H.
Researcher
Public Citizen's Health Research Group

Michael Carome, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009

Ian Roberts, M.B, B.Ch, F.R.C.P, FPH
Coordinating Editor
Cochran Injuries Group
Co-Director Clinical Unit
Clinical Trains Unite, London School of Hygiene & Tropical Medicine

Re: Docket No. FDA-2017-P-0867

Dear Petitioners:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet completed its response to the issues raised in your citizen petition received by the Division of Dockets Management on February 8, 2017. In your petition, you request that FDA immediately remove from the market hydroxyethyl starch (HES) intravenous (IV) solutions because (1) the solutions' risk outweighs their limited benefits and (2) there are a number of other, safer alternatives for the uses for which HES solutions are approved.

Because of the complexity of issues in your request, we have not been able to reach a decision on the petition at this time. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your requests.

Sincerely yours,

Peter Marks, M.D., Ph.D.
Director
Center for Biologics Evaluation and Research

cc: Division of Dockets Management (HFA-305)