DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

September 19, 2014

Sharon M. Moe, MD, FASN
President
American Society of Nephrology
1510 H Street, NW
Suite 800
Washington, DC 20005

Dear Dr. Moe:

Thank you for your letter of September 12, 2014, to the Food and Drug Administration (FDA or the Agency) about the shortage of peritoneal dialysis (PD) solution. FDA shares your concern and understands that PD is essential therapy in the treatment of kidney failure.
We understand the significant impact PD drug shortages are having on healthcare providers and their patients and we are doing everything within our authority to help alleviate the shortage and increase supplies in the marketplace. Please be assured that drug shortages are a key priority for FDA.

Regarding the PD shortage, in the United States (U.S.), there has been an increase in demand for PD solution, which along with other factors resulted in a shortage of this product on or about August 2014. FDA has been working actively with manufacturers to help resolve this shortage. At this time, Baxter Healthcare has informed us that they are continuing to produce and release as much product as possible within their current capacity and they are allocating their product to dialysis facilities to help meet patient needs. We have also been informed that Fresenius Medical Care North America has product available as well. More information can be found on FDA's Drug Shortages website, *http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm*.

In your letter, you ask FDA to "do everything possible to safely expedite the evaluation and licensure of PD solution manufacturing plants located outside of the United States that have the capacity to alleviate the current shortage, and to accelerate the import of PD solution from these plants." Currently, FDA is actively exploring alternate sources to help have additional product available as soon as possible to meet patient needs. Alternate sources are considered in cases when there is a shortage of a medically necessary drug that is critical to patients and the shortage cannot be resolved in a timely fashion with FDA-approved drugs. In these cases, FDA examines companies that manufacture drugs that are approved in non-U.S. markets and that may temporarily help meet critical patient needs in the U.S. When a firm is identified that is willing and able to import a drug approved in a non-U.S. market, FDA evaluates the drug to ensure that it is of adequate quality and that the drug does not pose undue risks for U.S. patients. Part of this evaluation process includes reviewing the status of the manufacturing site, the manufacturing process, and quality of the product including assessing the chemistry, clinical, and microbiology components of the product to evaluate safety for the patient. FDA also reviews the labeling of

the foreign product and a Dear Healthcare Professional letter to assure any differences in the foreign product are clearly identified to the health professionals. The review processes are completed as expeditiously as possible while still ensuring that the alternate source is of adequate quality and that the drug does not pose significant risks for US patients. While the Agency expedites this process as much as possible, we also need to ensure the safety and efficacy of products introduced into the U.S. market.

We will also continue to work with manufacturers, providers, patients, patient advocates, and other stakeholders to help minimize the PD drug shortage, protect patients, and help identify solutions to this serious shortage.

Thank you for contacting us regarding this matter. If you have further questions, please let us know.

Sincerely,

CAPT Valerie Jensen, R.Ph.
Associate Director
Drug Shortages Staff
Center for Drug Evaluation and Research