October 29, 2009

Mr. Jimmy R. Mitchell
Director
Office of Pharmacy Affairs, HSB/HRSA
Parklawn Bldg., Mail Stop 10C-03 5600
Fishers Lane
Rockville, MD 20857

RE: FUSA Sales of Venofer®

Dear Mr. Mitchell:

The purpose of this letter is to follow up on the discussion you had with representatives of Fresenius USA Manufacturing, Inc. ("FUSA") on the topic of limitations on sales by FUSA of the drug product Venofer® (iron sucrose injection, USP). As you requested, FUSA expressly authorizes the Office of Pharmacy Affairs ("OPA") to post this letter and its attachment on OPA's website, so that 340B covered entities may be fully informed of the reasons for the above-referenced limitations, and their options for obtaining Venofer.

Venofer® is manufactured for FUSA under sublicense from Luitpold Pharmaceuticals, Inc./ American Regent, Inc. (Shirley, NY) ("Luitpold/AR") and Vifor **(**International**),** Inc. In 2008, FUSA obtained an exclusive right and sublicense from Luitpold/AR to manufacture and sell Venofer® in the United States. Pursuant to this sublicense, FUSA is t h e "manufacturer," for purposes of federal drug pricing laws, of two Venofer® NDC- 11s marketed under the FUSA labeler code. The terms of its sublicense, however, limit FUSA to selling Venofer® only to independent, free-standing dialysis entities (and their distributors) and only for use by their end stage renal dialysis patients. Luitpold/AR sells it under its own NDC codes for uses outside FUSA'S field.

A 340B covered entity that is a free-standing dialysis entity may purchase Venofer® from FUSA at a discounted 340B program price. In the event that any facility that is not within FUSA's field of sublicense, whether or not a 340B covered entity, seeks to purchase Venofer® from FUSA, FUSA must refer that facility to Luitpold/AR as the appropriate, contractually-required manufacturer of the drug.

A more detailed description of FUSA's Venofer® licensing arrangement with Luitpold/AR is attached to this letter.

We appreciate your assistance in making FUSA's policy and the reasons for it known to the 340B community, so as to avoid any unnecessary confusion or delay for end-users in identifying the appropriate source from which they can obtain Venofer® for their dialysis patients. FUSA would be happy to answer any additional questions that you or other interested parties may have about the matters discussed in this letter.

James M. Jacobson
Senior Healthcare Counsel