DEPARTMENT OF VETERANS AFFAIRS
Office of General Counsel
Post Office Box 76
Hines IL 60141

April 22, 1993

In Reply Refer To: 025

Dear Member of the I.V. Solutions Industry:

I am writing to inform you of the Department of Veterans Affairs' (VA's) decision concerning the applicability of Section 603 of the Veterans Health Care Act of 1992 (P.L. 102-585; the Act) to I.V. solution products. We appreciate the participation of industry members in our conference to discuss the above issue held at Hines, Illinois, on February 19, 1993. In making its decision, VA has carefully considered all of the written and oral comments by members of the industry.

With regard to both large and small volume parenterals (LVPs and SVPs), we agree that those products which were previously marketed in glass containers without new drug application approvals (NDAs) by the Food & Drug Administration (FDA) should not be considered covered drugs under Section 603 of P.L. 102-585. The fact that FDA has required NDAs but no effectiveness clinical trials for these products when they were placed in plastic containers suggests that the plastic packaging NDAs were merely "paper" NDAs. However, all LVP or SVP products which have an NDA that required effectiveness clinical trials and all products which contain an ingredient with an NDA that required clinical trials are covered under the Act.

The same analysis will be applied by VA to peritoneal dialysis solutions (PDs) and irrigation solutions. Those products for which "paper" NDAs have been obtained without clinical trials will not be considered to be covered drugs under the Act.

Nutritional or caloric supplement solutions for which NDAs have been obtained after full clinical evaluations (e.g., animo acid solutions) are covered drugs under the Act. The fact that they are treated as generics in the competitive market place does not suggest to us that Congress intended for them to be exempted from Section 603 of the Act.

If your company has products which were previously believed not to be subject to P.L. 102-585 but which will be considered covered drugs under the above decision, please endeavor to report non-Federal Average Manufacturer Price and Federal ceiling price data as soon as possible to the Drug and Pharmaceutical Product Management Section at Hines, Illinois. VA's agreement and reporting packet are enclosed for your use.

If you have any questions concerning this decision or your company's reporting obligations, please do not hesitate to call me [(202) 523-3672] or one of our attorneys at the National Acquisition Center, Hines, Illinois [(708) 216-2505].

Thank you for cooperating with VA in its implementation of P.L. 102-585.

Sincerely yours,

for William E. Thomas, Jr.
Assistant General Counsel

Enclosure

MAN:gsd