assured of a homogenous distribution of the active ingredient, since it is initially in the form of a true solution. The Weight Variation requirement, combined with the assay and rubric definition, then provide complete assurance of the satisfactory quality of the lyophilized material in the individual final containers.

Consequently, it is our opinion that thereiis no basis for the statement in the third paragraph of your enclosure which reads "DPS feels the above standards are inadequate." (Incidentally, the sentence which immediately follows this quoted sentence does not appear to make sense as it reads--it would appear that the word "not" was left out of the second clause in this sentence.)

I trust these additional comments will be helpful to you in preparing your Amendments to the Federal Standard for Parenterals.

With kind regards,

Sincerely,

Edward G. Feldmann, Ph.D.
Director

EGF:pal
Enclosure