Fed. Std. No. 142A
Amendment - 1
March 17, 1970

FEDERAL STANDARD

PARENTERAL PREPARATIONS

This amendment, which forms part of Federal Specification Federal Standard No. 142A, dated October 31, 1966, was approved by the Commissioner, Federal Supply Service, General Services Administration, for the use of all Federal agencies.

PAGE 1

S2. Classification. Under "Type II-Nonaqueous" insert the following new class:

Class ? -- Undiluted.

PAGE 2

S4.2 Type II. Line 3, delete "two" and substitute "three."

S4.2.3 Class 3. Class 3 injections are undiluted liquid medicaments suitable for injection.

S4.9 Expiration date. Add the following at end of paragraph. "The expiration dates of antibiotics shall be based upon the first or original Food and Drug Administration certification. This certification shall be not later than 6 months after date of manufacture which for this purpose is defined by S4.7.3.

FSC 6505

S5.1 Add the following after first sentence.

"The 'Descriptions' included in U. S. P. and N. F. monographs that pertain to appearance or other attributes which can be specifically determined, by organoleptic examination or simple manipulations, shall be considered part of the requirements for the item."

Add the following new paragraph:

S5.8 Items requiring refrigerated storage. Items where the labeling in the procurement document includes storage under refrigeration, it is required that prior to delivery to the Government, the final, filled, immediate containers of such items shall be kept under constant refrigeration, except for the time required for necessary labeling, packaging, packing, and marking operations. The labeling, packaging, packing and marking operations shall be performed as expeditiously as possible and in no case shall the material be left out of refrigeration overnight. In addition, bulk solutions and in process material, for end items which are required to be stored under constant refrigeration, are to be stored under constant refrigeration. Bulk biologicals shall be stored in accordance with the applicable N. I. H. regulations.

PAGE 4

S6.2.1 Clarity of solutions. In line 2, following "type II, class 1;" insert "type II, class 3;".

PAGE 5

S6.3 Volume in final container (types I, II, and III). Delete in its entirety and substitute:

S6.3 Volume in final container (types I, II, and III). Final containers for types I, II, and III shall contain a volume in excess of the required (labeled) volume. The amount of excess fill volume in final containers shall be not less than that stated in the table in the U. S. P. under 'Volume in Containers'. For items with a labeled size not designated in the table in the U. S. P., excess recommended for the next larger size shall apply. For items in multiple dose containers labeled to yield a specific number of doses administered solely by jet hypodermic injection apparatus, the excess volume in the final container shall be not less than that stated in the table in the U. S. P. The method for determining the volume shall be as specified in the U. S. P. for single dose containers under 'Volume in Containers'."

S6.4 Delete in its entirety and substitute:

S6.4 Dry solids in final container (type IV). Final containers for type IV parenterals shall contain the required amount of ingredients.

S6.4.1 Type IV parenterals that are official articles in the U. S. P. shall comply with the Weight Variation Requirements for 'Sterile Solids' as described in the U. S. P. This requirement shall apply to sterile solids with or without added substances. In addition, sterile solids with added substances shall comply with the Content Uniformity requirements for 'Sterile Solids' as described in the U. S. P. In addition, sterile solids with or without added substances shall comply with the applicable paragraph under 'Container Content' in the U. S. P. Thus, Sterile Solids without added substances shall contain an average net weight not less than 93.0 percent and not more than 107.0 percent of the labeled amount of the article in the container and for Sterile Solids with added substances, the average of individual assays shall fall within the potency range of the individual monograph.

S6.4.2 Type IV parenterals that are official articles in the N. F. shall comply with the Weight Variation Requirements for 'Sterile Solids' as described in the N. F. This requirement shall apply to all sterile solids, with or without added substances. In addition, sterile solids, with added substances, shall comply with the Content Uniformity requirement for sterile solids as described in the N. F. In addition the average of the individual assays determined by the Content Uniformity Test shall fall within the potency range of the individual N. F. monograph.

S6.4.3 Type IV parenterals that are unofficial shall comply with the Weight Variation Requirements for 'Sterile Solids' as described in the U.S.P. This requirement shall apply to sterile solids, with or without added substances. In addition all sterile solids with added substances shall comply with Content Uniformity requirements for 'Sterile Solids' as described in the U.S.P. The individual containers shall be assayed by the assay method described in the procurement document, except that adjustments may be made so that the resulting final solution is of the same order as that obtained in the assay provided. In addition, sterile solids with or without added substance shall comply with the applicable paragraph under 'Container Content' in the U.S.P. Thus, Sterile Solids without added substance shall contain an average net weight not less than 93.0 percent and not more than 107.0 percent of the labeled amount of the article in the container and for Sterile Solids with added substances, the average of the individual assays shall fall within the potency range of the procurement document.

S6.5 Final containers for injectables. Delete the last two sentences and substitute:

"The final containers shall be sealed by fusion or by other means (whichever is specified in the procurement document) to prevent contamination or loss in contents. Closures for multiple-dose containers shall permit penetration by a sharp needle without detachment of fragments, and upon withdrawal of the needle at once recloses the container against contamination."

Add the following new paragraph:

S6.6.1 In process fill check. In process testing of volume of liquid fill in final containers or weight of sterile solids in final containers shall be performed at predetermined intervals of no greater than one hour. Each filling machine and each filling nozzle of multiple nozzle filling machines shall be checked during the predetermined interval.

PAGE 8

S6.10.1 In table, in column headed "AQL (percent defective) " - for Major C, delete "6.0" and substitute "1.0."

S6.10.2 Testing. Lines 7 through 9 - Delete in their entirety and substitute:

"Sampling for tests (A) and (C) shall be in accordance with the designated Inspection level in table III, unless otherwise indicated." Under heading "Tests" for Test (B) - following "Contents (type IV)" add "**."

In paragraph "**Special sampling" in line 3, delete "(D) and (E)" and substitute "(B), (D) and (E)."

PAGE 9

Table IV. Classification of defects. Insert a new column as follows:

Nonaqueous (type II) Undiluted (class 3)

Insert "X's in the new column for Major A; 101, 102, 103, and 104; Major B 151.