

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10215

-2-

<u>Name</u>	<u>Additional Requirement</u>	<u>Comment (EGF)</u>
Benzonate Capsules, NF, 100 mg, 100s	Identity	The NF monograph specifies two identity tests and both of them are quite specific. Additional tests for this purpose are redundant.
Ammonia Spirit, Aromatic, NF, 1/4 pt	Removal torque for closure on immediate container	The NF monograph specifies packaging in a "tight container" which is defined in the General Notices, and which provides adequate protection for the product.
Hydralazine Hydrochloride Tablets, NF, 25 mg, 100s	Weight Variation	The NF monograph includes a Content Uniformity test, which is even more precise than the Weight Variation test, making it superfluous for this item.
Methylprednisolone Sodium Succinate for Injection, NF, Equivalent to 1 Gram of methylprednisolone	Content Uniformity	Contrary to DPSC statement, the NF monograph does require compliance with Content Uniformity specification.
Methylprednisolone Sodium Succinate for Injection, NF, Equivalent to 40 mg of methylprednisolone	Content Uniformity	(ditto; see above)
Methylprednisolone Sodium Succinate for Injection, NF, Equivalent to 125 mg of methylprednisolone	Content Uniformity	(ditto; see above)
Soap, Green, NF, 25 lb	Vegetable Oil (Cottonseed Oil, Corn Oil, or Soya Bean Oil)	NF monograph does require use of a suitable vegetable oil, and specifically excludes coconut oil or palm kernel oil. Additional requirement is redundant.