

February 27, 1974

Comments on "Additional Requirements" listed by DOD/DPSC regarding selected National Formulary (NF) articles, appearing in second increment of DOD response to Senator Nelson's request of January 17, 1974. These comments prepared by Edward G. Feldmann, Ph.D., American Pharmaceutical Association.

[Note: The listing submitted by DOD was not page numbered, nor were items in alphabetical order. These comments are presented on drug items in the same order that they appeared on the DOD listing.]

<u>Name</u>	<u>Additional Requirement</u>	<u>Comment (EGF)</u>
Chloral Betaine Tablets, NF, 0.50 Gram, 30s	Additional test requirement for the active ingredient (Melting Range)	Melting Range of Chloral Betaine cannot be determined either with accuracy or consistency due to inherent nature of compound. Hence, inappropriate as a standard or specification. Therefore, it is in the NF monograph, but is given under the heading of "Description" to distinguish from an enforceable standard.
Cyproheptadine Hydrochloride Tablets, NF, 4 mg, 100s	Free Hydrochloric Acid	There is no reason to expect any free hydrochloric acid to be present, and even if there were, it would be a micro-quantity since there is only a total of 4 mg of active ingredient per tablet. Moreover, in light of the composition of gastric fluid there is no medical purpose served by this limit.
Aspirin, Phenacetin, and Caffeine Tablets, NF	Moisture Content	The NF monograph provides a test and limit for the deterioration product which would result from any moisture present. This is a more meaningful standard in judging the quality of the product.