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Comments on Blend Uniformity from the Generic Pharmaceutical Association (GPhA) to the Advisory Committee for Pharmaceutical Sciences, Food and Drug Administration)

Good Morning ladies and gentlemen. My name is Steve Lonesky and I am with Teva USA which is a member of the Generic Pharmaceutical Association and am speaking to you today on behalf of the Association. GPhA thanks the FDA for the opportunity to contribute to the dialog concerning the issue of blend uniformity.

Briefly, GPhA endorses PQRI's Blend Uniformity proposal with the exception of the 4% RSD for the cGMP Compliance Requirement. We believe that this requirement is unnecessarily limiting and will result in unwarranted investigations and testing of actually compliant product.

The generic industry views blend uniformity as a good tool for the development and validation phases of manufacture but must be carefully considered in light of the well-documented problems associated with the "sampling phenomena" of a dynamic powder blend. Sampling phenomena are well documented in the literature. We must have a way to deal with the occasional sample result that just does not make sense and fit the data set, when we know it is most likely due to the sampling. We can pick up a tablet and assay it. There is no question what the sample is and what the result represents. This is not true of a sample pulled from a powder bed that is in constant motion. To this end we must have this two-tiered approach. Inspectors should also take this into consideration when reviewing product data and investigations performed by a firm when a result does not conform to the intended spec. Because this is only one tool to determine the quality of a product, and has a significant flaw associated with the process of obtaining a reliable sample on a consistent basis, this method should not be applied to routine production of commercial product.

In addition, we are concerned with the unequal application of blend uniformity requirements by the agency. If in fact blend uniformity is indeed so important in the manufacture of quality drugs, it would seem prudent that the rules apply to submitters of NDAs as well as ANDAs.

Again thank you for the opportunity to contribute the generic industry's views on this issue.

Thank you