By Electronic Submission
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852.

Comments on Draft Guidance for Industry Considerations in Demonstrating Interchangeability with a Reference Product [Docket No. FDA–2017–D–0154]

Dear Madam/Sir,

Introduction – RetireSafe, a nationwide senior advocacy organization, welcomes the opportunity to comment on this draft guidance concerning Interchangeability.
RetireSafe represent activists and supporters nationwide who look forward to the promise of increased access that biosimilars and interchangeables represent. This promise is expanded by the draft guidance on interchangeability that was released in January. While we look forward to this increased access we do so with an eye clearly focused on safety. We believe that any early failures, health problems, label confusion, the inability to efficiently track medicines or lack of communication between doctors, patients and pharmacists could abnormally delay both the continued development and release of biosimilars and the granting of the interchangeability designation. These failures could also have a grave effect on adoption of biosimilars by health care providers. Our comments, therefore, are focused on safety.

Labeling – The label should be clearly marked as to its designation as interchangeable with a clear definition of how FDA defines interchangeability. This clear labeling will reduce the confusion at the provider level and at the pharmacy level as they both work to comply with the FDA and their state's laws concerning interchangeable products.

Naming – As we have recommended in the past we believe that interchangeable products should have its own unique suffix and that the suffix should be meaningful and carry information to help identify the manufacturer. This approach will aid in tracking the product while also reducing confusion. We believe it is extremely unadvisable for the interchangeable product to have the same suffix as the reference product.

Multiple interchangeable products for a reference product – FDA does not define the criteria for pharmacy level substitution when there are multiple interchangeable products for a reference product. When the manufacturer applies for interchangeability do they have to supply data showing that they are also interchangeable with the other products that have obtained interchangeability with that reference product or, for that matter, with other biosimilars? This confusion needs to be resolved so manufacturers are encouraged to apply for the interchangeability designation and to reduce the confusion at the provider, pharmacy and the state regulatory levels.

Interchangeability for specific indications – While we have recommended in past discussions concerning biosimilars that a manufacturer should have the ability to apply for a biosimilar that is approved for a subset of the indications approved for the reference product and that the FDA should have the ability to approve a biosimilar for just a subset of reference product indications, we feel the interchangeable product should be treated differently. For safety reasons, we feel that an interchangeable product should be required to show interchangeability with all indications of the reference product. While a provider is acutely aware of the patient's health status and the indications

the reference biologic will treat, the pharmacist may not, this could result in confusion if an interchangeable product is not interchangeable for all the reference products indications.

Substitution – The final guidance on interchangeability is critical given the fact that the doctor and the pharmacist must feel confident that when, or if, the product is substituted the patient will receive the same level of treatment. If this confidence is not attained the substitution will not occur and the promised savings will not be realized. The importance of this guidance is further magnified by the large number of states that have laws already in place concerning interchangeable biologic products most, if not all, require communication between the doctor and the pharmacist when substitution occurs. The FDA draft guidance and the state laws all deal directly and in detail about how substitution will be regulated at the pharmacy, including adherence to the doctor's prescription, adherence to the drugs label and required communication between the pharmacist and the doctor. What is missing is when that substitution occurs outside of the pharmacy.

When the FDA issues the final guidance on interchangeability the FDA will work aggressively to ensure that the guidance is adhered to. If a pharmacist substitutes a biosimilar that has not been deemed interchangeable for a reference product, the FDA or the state will use whatever means available to stop the action and to make sure it doesn't happen again. They do this to maintain the safety of the patient. RetireSafe thinks that the FDA cannot continue to maintain the safety of the patient without extending their final guidance to include the entire supply line. The FDA monitors the manufacturing and shipping of pharmaceuticals to ensure the safety of the patient. If a biosimilar was substituted for a reference product during shipping the FDA would immediately get involved. RetireSafe thinks this unauthorized substitution is already taking place when a PBM or insurance company removes a reference product from its formulary. This creates a barrier to access for the patient and, in many cases, forces a substitution, a substitution that would not be tolerated at the pharmacy. We think the recent change to the purple book concerning substitution reveals the intent of the FDA to limit unauthorized substitution but it focused on the pharmacy rather than on the entire supply line and therefore would not limit this "outside the pharmacy" type of unauthorized substitution.

It is RetireSafe's stance that, whether through the interchangeability final guidance or though recommendations to HHS or Congress, the FDA needs to aggressively protect the patient's safety by eliminating this type of unauthorized substitution.

Conclusion – RetireSafe recognizes the difficult task the FDA has in ensuring the safety of patients and commends the FDA on the interchangeable draft guidance. Biologics are a wonderful but complicated medicine. We want the increased access that biosimilars and interchangeables offer. We think that ensuring patient safety at the beginning will earn the confidence of the patient, the doctor and the pharmacist and will allow us to realize the savings offered by biosimilars and interchangeables.

Thank you for the opportunity to submit these comments,

Thair Phillips
President/CEO RetireSafe