However, the FDA is not likely to designate products as fingerprint-like similarity—this is only useful for discussion with the FDA in reducing clinical study requirements. The reason why the FDA will not provide specific designation is to avoid developers claiming any superiority of their product over others.

2.2.5.10 Extrapolation

Extrapolation refers to the allowance of all indications licensed or a limited number of multiple indications licensed for the use of the originator product. The basis of this allowance resides in the importance given to structural and functional similarities, which, in turn, assures that the biosimilar product will have the same effectiveness and side effects. There is a huge hue and cry by the originator companies suggesting extraordinary scientific reasons why this should not be allowed; all of these arguments are driven to keep biosimilar products under the shadow of a doubt.

2.2.5.11 Label copy

The FDA has established that the label copy can be the same as that of the originator, somewhat similar to what is allowed for generic pharmaceutical products. There remains a differentiation of naming of the product; in its first approval, the FDA has required a four-letter suffix to the generic name but states that this issue is still not resolved. AbbVie has filed a citizen's petition protesting the use of identical label and states that whereas the FDA has presented alternate views, these views were retracted in the final guidance issued in 2015.

2.2.5.12 Interchangeable biosimilars

The BPCI Act allows for a designation of a biosimilar product as interchangeable if upon switching and alternating with the originator product, there is a reduction in clinical effectiveness and no increase in side effects as demonstrated in a clinical setting. The FDA anticipates reviewing two applications per year for interchangeable status. Before a product can be evaluated as interchangeable, it must first be a proven biosimilar product; it is for this reason that most developers are likely to achieve approval of their product as biosimilar first and then pursue an interchangeable status; the FDA is yet to provide any guidance on these protocols, but there is sufficient literature available to design these studies. EMA does not have any such category. However, several countries in Europe including France have declared that the government will only reimburse for a biosimilar product for new patients when an originator product is prescribed.

2.2.5.13 Pediatric waiver

For the purpose of pediatric use, biosimilar products are considered new drugs and the sponsor is required to submit pediatric study waiver and in all instances only those applications that are licensed for the originator will be allowed.