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Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Comment on Food and Drug Administration Draft Guidance "Labeling for Biosimilar Products"

Submitted electronically via www.regulations.gov

June 3, 2016

Dear Commissioner Califf:

CSRO is a national organization composed of state and regional professional rheumatology societies formed to advocate for excellence in rheumatologic care and to ensure access to the highest quality care for patients with rheumatologic and musculoskeletal disease. We write to comment on the "Labeling for Biosimilar Products" draft guidance released by the Food and Drug Administration (FDA) in March 2016.

The guidance proposes that original clinical data generated by a biosimilar manufacturer generally should not be included on the label, unless such inclusion is necessary "to inform safe and effective use by a health care practitioner." Instead, FDA recommends that the biosimilar label should include the clinical data supporting safety and efficacy of the reference product.

CSRO believes that the reference product data should be included on the biosimilar label for those indications for which the biosimilar is approved, but we urge the agency to also include any original clinical data generated by the biosimilar applicant. We acknowledge FDA's concern that the clinical data for the reference product and the clinical data for a biosimilar serve different purposes: the former is intended to establish safety and efficacy, while the latter is intended to establish similarity. However, we disagree with FDA's assertion that inclusion of the biosimilar clinical data would "cause confusion" among practitioners. In fact, we believe that clinicians would be interested in bioequivalence data and take these data into account when making prescribing decisions.

The guidance further notes that the text between the two labels does not have to be identical. Instead, the labels should include current information that is "necessary for the safe and effective use of the biosimilar product." CSRO believes that this practical approach will provide the agency with the flexibility to incorporate clinical data as it is generated by each manufacturer. We have always maintained that these products are not traditional generics and can never be identical; as such, their labels should reflect any differences, as appropriate.

In the guidance, FDA acknowledges that there will be times when a biosimilar is licensed for fewer indications than the reference product. In those cases, the guidance notes that information related to the indications unique to the reference product would not be included in the biosimilar label, unless it is necessary to "help ensure safe use[.]" If the information must be included to ensure safe use, it cannot be presented in a way that implies that the biosimilar is approved for those indications. We are concerned that simply omitting information is insufficient to convey to clinicians that the biosimilar is not approved for certain indications. In addition to not including the information, we urge FDA to require the biosimilar to explicitly list on its label the reference product indications for which it is and is not approved.

In the guidance, the FDA proposed that a biosimilar label must state that it is a biosimilar. We consider this an important piece of information and support the agency's decision to include it in the product label. CSRO also asks the agency to require that the biosimilar label state whether or not the product has been approved as "interchangeable" with the reference product. In the traditional generics world, there are no degrees of similarity: the agency either approves a product as a generic, or not. We are concern ed that most clinicians will believe that this paradigm applies to biosimilars and that the distinction between "biosimilarity" and "interchangeability" will be lost in the real world, even though the statute provides separate definitions and evidentiary thresholds for these terms. A statement indicating whether the product is interchangeable or not will help combat this potential confusion.

CSRO thanks the agency for issuing the biosimilar labeling guidance and we hope that you will incorporate our recommendations into the final guidance. Thank you for your consideration.

Sincerely,

Michael Stevens, MD
President