

**COMMENTS SUBMITTED ON BEHALF OF THE BIOLOGICS COMMITTEE FOR THE
FOOD, DRUG AND COSMETIC LAW SECTION TO THE U.S FOOD AND DRUG
ADMINISTRATION REGARDING THE AGENCY’S DEFINITION OF THE TERM
“BIOLOGICAL PRODUCT”**

Docket No. FDA-2018-N-2732

<https://www.federalregister.gov/documents/2018/12/12/2018-26840/definition-of-the-term-biological-product>

Food, Drug and Cosmetic Law #1

February 25, 2019

On behalf of the New York State Bar Association’s Biologics Committee for the Food, Drug and Cosmetic Law Section we are pleased to offer these comments regarding the U.S. Food and Drug Administration’s (FDA) Definition of the term “Biological Product” (FDA-2018-N-2732).

Committee Purpose:

The purpose of the Biologics Law Committee is, in part, to keep the biologics and biosimilars industry and legal practitioners up to date and provide practical advice concerning issues that are of interest to the industry. Such issues involve the U.S. Food and Drug Administration’s regulation of biological products, including its implementation of the Biologics Price Competition and Innovation Act (BPCIA) and related reimbursement and substitution rules, interactions with the Food and Drug Administration, Federal Trade Commission, and state agencies, and legislative developments. The Committee also follows the recent trends in litigation involving consumer class actions, labeling claims, biosimilars “patent dance,” among others.

The Committee also seeks to engage members in programming and activities to contribute to the development of sound laws, policies, and regulations concerning the biologics industry, including biosimilars.

Committee Position(s):

The Committee supports the FDA’s position on the proposed changes to the term protein which would mean “any alpha amino acid polymer with a specific defined sequence that is greater than 40 amino acids in size, and the term *chemically synthesized polypeptide* would mean any alpha amino acid polymer that: (1) Is made entirely by chemical synthesis and (2) is greater than 40 amino acids but less than 100 amino acids in size.”

The reason for this support comes from the FDA’s intent that this change conforms to the statutory definition enacted in the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). We support this technical change to make it easier for biological products to have their own distinct identity from chemically made products.

Conclusion:

Thank you for the opportunity to allow us to submit comments on this important issue. We welcome the opportunity to serve as a resource to you if you have further questions as you proceed further in your deliberating process.

Food, Drug and Cosmetic Law Section Chair Brian Malkin, Esq.
Committee on Biologics Law Chair Ron Lanton III, Esq.