AIPLA
American Intellectual Property Law Association

September 19, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: AIPLA Comments on Docket No. FDA-2018-N-2689, Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments

Dear Sir or Madam:

The American Intellectual Property Law Association (AIPLA) is pleased to have this opportunity to provide comments on the Food and Drug Administration's (FDA) Federal Register Notice entitled "Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments" dated July 25, 2018, and the Public Hearing held on September 4, 2018.

AIPLA, headquartered in the United States, is a national bar association of approximately 13,500 members who are primarily practitioners engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping to establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

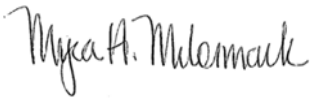
AIPLA's primary interest is legal matters pertaining to intellectual property, and AIPLA has identified aspects of the Federal Register Notice and Public Hearing that may impact our membership by impacting intellectual property rights. These aspects include, for example, (1) possible changes to the Purple Book to include patent and exclusivity information (question 2), (2) possible changes related to licensing biosimilar and interchangeable products for fewer than all conditions of use for which the reference product is licensed (question 7), and (3) possible application of "umbrella exclusivity" to biological products (question 8).

AIPLA requests that before making changes related to the Federal Register Notice and Public Hearing, FDA consider possible implications on intellectual property rights, the patent litigation scheme provided by the Biologics Price Competition and Innovation Act of 2009 (BPCIA), and how that scheme compares with the patent litigation scheme provided by the Drug Price Competition and Patent Term Restoration Act of 1984 (referred to as the Hatch-Waxman Act). AIPLA also requests that FDA provide detailed notice of any proposed changes related to the Federal Register Notice and Public Hearing and its reasons for proposing those changes, as well

as opportunity for meaningful comment from AIPLA and other stakeholders. Furthermore, taking into account the existing legislations, AIPLA further requests that the FDA undertake an analysis of the implications on intellectual property of any proposed changes that the FDA might implement, and publish the results for further public comments.

AIPLA supports the FDA's efforts to enhance competition and innovation in the biological products marketplace and appreciates the opportunity to provide comments on issues that may impact intellectual property and our membership.

Sincerely,



Myra H. McCormack
President
American Intellectual Property Law Association