February 18, 2020

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Bridging for Drug-Device and Biologic-Device Combination Products (FDA-2019-D-5585)

Submitted electronically

Dear Sir/Madam,

Biocom is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,300 members dedicated to improving health and quality of life, Biocom drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products. California's life sciences industry generates nearly $346 billion in annual economic output, boosts the state's total gross product by $195.8 billion, supports almost 1.3 million jobs, and increases labor income by more than $104 billion per year[1].

Biocom appreciates the opportunity to offer comments on the Food and Drug Administration (FDA) draft guidance *Bridging for Drug-Device and Biologic-Device Combination Products* ("draft guidance") and thanks the agency for delivering this draft guidance by the deadline set in the Prescription Drug User Fee Act (PDUFA) VI goal letter.

Combination products are on the rise as more chronically ill patients are relying on medical products that include a combination of drugs, devices, or biologics for their care. Developing combination products presents many unique challenges that are often different than those associated with traditional drug development. Because of these inherent complexities, in some circumstances, the agency may require more data and information to address additional questions of safety and effectiveness raised by the proposed use or function of a constituent part in the combination product. In these cases, bridging can possibly be used to leverage information from an earlier phase of the development program or

[1] *Biocom 2019 Economic Impact Report Databook*

another development program to support the combination product for which a sponsor is seeking approval.

Biocom thanks the agency for providing guidance on how to conduct a gap analysis to develop a bridging approach and providing three examples. We respectfully offer the comments and recommendations below.

Clarification on Reference to Master Files

In the introduction of the guidance, the agency states "For certain types of applications, the use of information from another development program may require that the applicant own the information or have a right of reference." The reference (footnote 6) refers to 21 CFR 314.3 as an example for right of reference. Device manufacturers provide device constituent information in a master file and require a right of reference (via letter of authorization) to support the customer's New Drug Application (NDA) or Biologics License Application (BLA) for their combination products. However, this guidance appears to only address the owners of the future combination products application and does not appear to include interactions that occur for component/device constituent manufacturers for these devices.

Biocom recommends that the agency add language that states the FDA also permits reference to master files containing information that is relevant to an NDA or BLA application for combination products with device constituents. The agency's approach to the terminology for types of master files used for products regulated under the Public Health Service (PHS) Act has generally tracked its approach to the types of device master files (DMFs) (e.g., Type II, Type III) used for products regulated under the Food, Drug & Cosmetic (FD&C) Act. Biocom recommends that the agency add the bold to the end of the sentence that ends on line 41: "For certain types of application, the use of information from another development program may require that the applicant own the information or have a right of reference **(i.e. to a Device Master File, 510(k), NDA, etc.)."**

Additional Examples on Wearable or On-Body Injectors

The agency presents three case examples for bridging of data from a prefilled syringe to an auto-injector, from on auto-injector to another auto-injector, and from combination product using the same device and different drug. This guidance does not address or provide clarity on how to bridge information to support wearable injectors or on-body injectors. It is recommended that such an example be included since these represent more complex combination products that the agency can expect to see being submitted with increased frequency. Transparency on how to bridge data from device constituent manufacturers to drug/biologic final combination product marketers/applicants is needed to help streamline the process for market authorization. Please add another example to illustrate the bridging of data from a prefilled syringe to a device with complexity (for example, an on-body injector co-packaged with a prefilled syringe and filled at the time of use).

Thank you again for the opportunity to provide these comments. We look forward to a continued dialogue with the FDA on improving the regulatory framework for combination products. If you have any questions about these comments, please contact Brittany Blocker, Manager of Regulatory Affairs at bblocker@biocom.org.

Sincerely,

Joe Panetta
President and CEO
Biocom