Platform Technologies Designation Program: Highlights of statutory language

- CBER Regulated Products
- Phillip Kurs, J.D.

Introduction in Consolidated Appropriations Act

- Designation program created as part of 2022 Consolidated Appropriations Act
- Section 2503 of the PREVENT Pandemics Act (part of the Consolidated Appropriations Act) amended the Federal Food Drug, and Cosmetic Act to add “Sec 506K Platform Technologies”

Platform Technology Designation Criteria

- "A platform technology incorporated within or utilized by a . . . biological product is eligible for designation as a designated platform technology under this section if
  - (1) the platform technology is incorporated in, or utilized by, . . . a biological product licensed under section 351 of the Public Health Service Act;
  - (2) preliminary evidence . . . demonstrates that the platform technology has the potential to be incorporated in, or utilized by, more than one drug without an adverse effect on quality, manufacturing, or safety; and
  - (3) data or information . . . indicates that incorporation or utilization of the platform technology has a reasonable likelihood to bring significant efficiencies to the drug development or manufacturing process and to the review process"

Platform Technology definition

- "Definitions.—For purposes of this section:
  - (1) The term 'platform technology' means a well-understood and reproducible technology . . . that the Secretary determines to be appropriate, that the sponsor demonstrates—
    - (A) is incorporated in or utilized by . . . biological product and is essential to the structure or function of such . . . biological product;
    - (B) can be adapted for, incorporated into, or utilized by, more than one drug or biological product sharing common structural elements; and
    - (C) facilitates the manufacture or development of more than one drug or biological product through a standardized production or manufacturing process or processes."

Rule of Construction

- "Nothing in this section shall be construed to—
  - alter the authority of the Secretary to ... license biological products pursuant to section 351 of the Public Health Service Act, including standards of evidence and applicable conditions for approval or licensure under the applicable Act; or
  - confer any new rights with respect to the permissibility of a sponsor of an application for a . . . biological product referencing information contained in another application submitted by the holder of . . . a license under section 351(a) of the Public Health Service Act.''

Knowledge and Control of Manufacturing Process

- "As a scientific matter [for 351(a) BLAs] . . . a license holder is expected to have knowledge of and control over the manufacturing process for the biological product for which it has a license"
  - Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product; Guidance for Industry (April 2015)


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