U.S. FOOD & DRUG ADMINISTRATION

BIOSIMILARS ACTION PLAN:
Balancing Innovation and Competition

2018 BAP Activity Summary of Accomplishments
April 2024

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1. EXECUTIVE SUMMARY

The Food and Drug Administration (FDA) accomplished numerous priority deliverables included in the 2018 Biosimilars Action Plan (BAP), summarized in this Executive Summary.

In July 2018, the FDA released the Biosimilars Action Plan (BAP), which outlines the Agency's commitment to encouraging innovation and competition among biological products and the Agency's role in expanding access to biosimilars for the American public. This includes describing actions FDA can take to encourage a more competitive market, increase efficiency and transparency for sponsors to support future biosimilar development, and advance public health. Since then, the Agency has made significant strides in fulfilling the deliverables and activities outlined in the 2018 BAP. The 2018 BAP focuses on four key areas, and outlines priority deliverables within each, that define FDA's vision for supporting biosimilar development, promoting fair competition, and developing materials to improve understanding about biosimilars and the FDA's approval process. This executive summary highlights some of the achievements made in each key area.

The first key area focuses on improving the efficiency of the biosimilar and interchangeable biosimilar product development and approval process. FDA transitioned the Therapeutic Biologics and Biosimilars Staff (TBBS) to the Office of Therapeutic Biologics and Biosimilars (OTBB) within the Office of New Drugs (OND) in the Center for Drug Evaluation and Research (CDER) in 2019. OTBB serves as the overarching organizational structure to support biosimilar review programs, policy development, and communication activities. Another step to aid in biosimilar review efficiency was the development of application review templates specifically for 351(k) Biologics License Applications (BLAs). The templates were formatted to the data and information inherent to a 351(k) BLA and approval standards specific to biosimilars and interchangeable biosimilars. FDA also sought to improve the efficiency of biosimilar development programs by holding public workshops to discuss considerations and potential approaches to facilitate progress in this area.

The second key area concentrates on maximizing scientific and regulatory clarity for the biosimilar product development community. FDA developed seven additional guidances covering a range of topics to provide more predictability and to further clarify the biosimilar and interchangeable biosimilar regulatory pathway. This includes developing a revised Questions and Answers (Q&A) guidance on biosimilar development and the Biologics Price Competition Innovation Act of 2009 (BPCI Act), which included a Q&A on post-approval manufacturing changes. FDA also held a public meeting to encourage dialogue on policy actions that FDA should consider as part of ongoing enhancement of the biosimilar program. FDA enhanced the Purple Book: Database of Licensed Biological Products, transitioning it from a document list to a searchable database with information about FDA-approved biological products, including biosimilars, interchangeable biosimilars, and their reference products. The Purple Book also includes information about newly approved or withdrawn BLAs, as well as reference product exclusivity determinations according to commitments under the 2017 reauthorization of the Biosimilar User Fee Act III (BsUFA II).

The third key area focuses on developing effective communications to improve understanding of biosimilars among patients, healthcare providers, and payors. FDA developed materials as part of FDA's Biosimilars Education and Outreach Campaign for patients and stakeholders. For example, FDA created an infographic and website content for patient audiences, and staff participated in stakeholder webinars and conducted outreach to help educate patient audiences. FDA also developed educational materials for healthcare providers and pharmacists, including a biosimilar curriculum toolkit for use in medical, nursing, and pharmacy schools, webinars for continuing education units (CEUs), and held a Reddit forum for pharmacists. FDA engaged payors and other stakeholders with focused webinars to emphasize the rigor of the development and approval process.

FDA also conducted research to test materials and gather feedback from stakeholders on additional topics for future education efforts.

The fourth key area focuses on market competition, specifically reducing gaming of FDA requirements or other attempts to unfairly delay competition. FDA is continuing work to clarify its position on issues affecting reference product exclusivity, and coordinated with the Federal Trade Commission (FTC) to, among other things, evaluate whether firms are using FDA statutory requirements to inappropriately delay approval of biosimilar or interchangeable biosimilar competitors. FDA worked collaboratively with industry and legislators to address any loopholes that may delay competition beyond the exclusivity periods envisioned by Congress and addressed circumstances in which drug makers delay the entry of biosimilar or interchangeable biosimilar development and competition. FDA also released a draft guidance on Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products to discuss considerations for presenting data and information about reference or biosimilar products in promotional materials in a truthful and non-misleading way.

The deliverables highlighted in this executive summary demonstrate FDA's commitment to supporting the development and approval of high quality, safe, and effective biosimilars and interchangeable biosimilars for the American public. This work exhibits the Agency's dedication to their critical role to ensure the United States (U.S.) remains a driving force in medical innovations and facilitating increased access to biosimilars. FDA expects continued expansion in the number of approved biosimilars and interchangeable biosimilars in the upcoming years and the need to continue this important work.

2. BACKGROUND

The 2018 BAP set a strategic vision for FDA's commitment to supporting biosimilar and interchangeable biosimilar product development and approval.

Biological products (biologics) are the fastest-growing class of medications in the United States and account for a substantial and growing portion of healthcare costs.[1] The BPCI Act created an abbreviated approval pathway to help provide patients with greater access to safe and effective biological products, furthering FDA's mission to protect and promote public health by helping to ensure that biosimilars are safe, effective, and high-quality treatment options for patients.

The 2018 BAP[2] outlines FDA's commitment to enhance and facilitate the review and approval of biosimilars and interchangeable biosimilars products in the United States. The 2018 BAP includes four key areas, priority deliverables, and specific activities to support the strategic vision for FDA's future. These FDA efforts encourage innovation and competition for biologics and facilitate the development of safe and effective biosimilars at lower costs for patients.

This 2018 BAP Activity Summary serves as a progress report of FDA's accomplishments and highlights the completed activities and priority deliverables. These activities were completed in collaboration with many offices in CDER and FDA, as well as with fellow regulatory agencies and external stakeholders.

[1] Biosimilars in the United States 2023-2027: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027

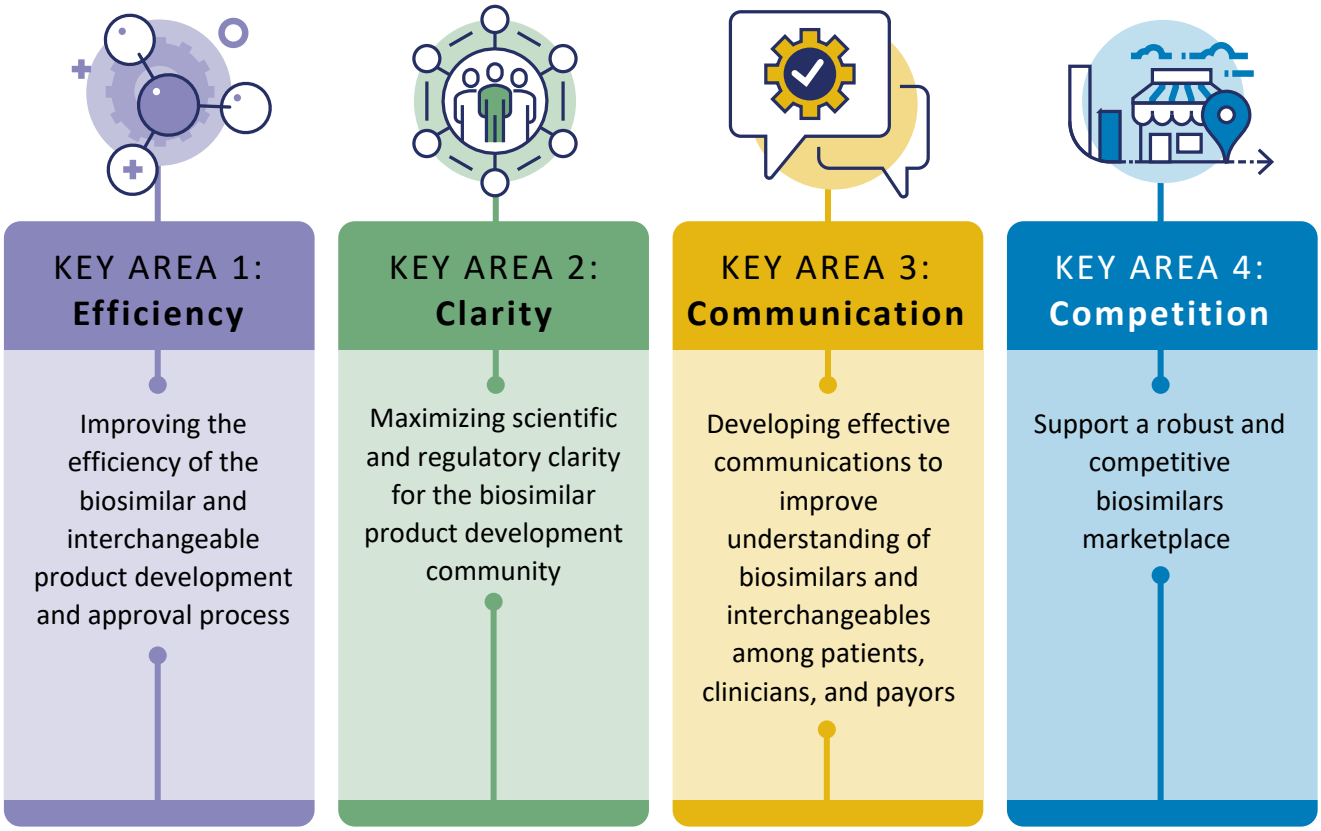
[2] 2018 Biosimilars Action Plan (BAP): https://www.fda.gov/media/114574/download

3. BAP ACTIVITIES AND DELIVERABLES

The Agency accomplished numerous priority deliverables associated with the four key areas outlined in the 2018 BAP, summarized in detail within this section.

Completed deliverables and activities are organized into four sections by the key area, which are depicted below in Figure 1 as efficiency, clarity, communication, and competition. Within each key area are priority deliverables that relate to the broader vision for that key area. The 2018 BAP also included 11 key actions to support the innovation and competition among biologics and the development of biosimilars. Key areas, priority deliverables, actions and activities are summarized in Sections 3.1 – 3.4 below.

Figure 1. 2018 BAP Key Areas



3.1 Key Area 1: Improving the Efficiency of the Biosimilar and Interchangeable Product Development and Approval Process

Improving the efficiency of the biosimilar and interchangeable product development and approval process was the focus of Key Area 1. Implementing the biosimilar and interchangeable biosimilar development and approval process to maintain efficient, predictable, and science-based pathways with the aim of reducing the time, uncertainty, and cost of drug development can help to support a competitive marketplace through the efficient approval of lower cost alternatives. A tabular listing of the priority deliverables and the notable accomplishments associated with Key Area 1 are included in Table 1.

Table 1. Key Area 1. Priority Deliverables and Notable Accomplishments

Priority Deliverable	Notable Accomplishments
Increase the efficiency of the review of biosimilars and interchangeable biosimilars by developing application review templates specifically for 351(k) BLAs.	FDA developed application review templates specifically for 351(k) BLAs including Comparative Analytical Assessments (CAA), BMER, and 351(k) discipline-specific filing checklists, which have been in use since July 2019. Additional internal supportive training was developed and provided to support these templates which include the CAA and BMER formatting video and Lunch and Learn sessions.
Transition the TBBS to the OTBB to improve coordination and support of all activities related to biosimilar and interchangeable biosimilar product development and approval.	In March 2019, FDA transitioned TBBS to OTBB within the OND in CDER. Since the transition, OTBB implemented BsUFA II commitments, helped define BsUFA III commitments, and continues to grow as an organization and take on more responsibilities under BsUFA III.
Develop and implement associate director for biosimilar positions in key scientific review discipline organizations.	FDA implemented Associate Director for Biosimilars positions in various offices, including Office of Combination Products (OCP), Office of Biotechnology Products (OBP), and Office of Biostatistics (OB). *Subsequently, OCP created the Therapeutics Biologics Program (TBP) within their Immediate Office.
Develop information resources and development tools that can assist biosimilar sponsors in developing high quality biosimilar and interchangeable biosimilar products using state-of-the-art techniques.	FDA has made progress toward identifying and clarifying general considerations associated with product-class specific guidance. OCP/Division of Applied Regulatory Science (DARS) led efforts to complete an initial set of pilot clinical Pharmacokinetic/ Pharmacodynamic (PD/PK) studies, hired a contractor to help develop an evidentiary framework, conducted a 2-day public workshop[3] from September 20-21, 2021, regarding pharmacodynamic biomarkers for biosimilar development and approval, and published a CDER Spotlight Article[4] on pharmacodynamic biomarkers. DARS continues to publish results from the completed research as well as pursue the in-silico research aspects of this work as of 2023. FDA hosted a workshop[5] in September 2022 discussing approaches to streamline the efficiency of biosimilar development programs.

[3] Public Workshop: Pharmacodynamic Biomarkers for Biosimilar Development and Approval (September 2021): https://www.fda.gov/drugs/news-events-human-drugs/pharmacodynamic-biomarkers-biosimilar-development-and-approval-09202021-09212021

[4] CDER Spotlight Article Pharmacodynamic Biomarkers: Their Role in Biosimilar Product Development: https://www.fda.gov/drugs/news-events-human-drugs/pharmacodynamic-biomarkers-their-role-biosimilar-product-development

[5] FDA Workshop: Increasing the Efficiency of Biosimilar Development Programs (September 2022): https://www.fda.gov/drugs/news-events-human-drugs/fda-workshop-increasing-efficiency-biosimilar-development-programs-09192022

3.2 Key Area 2: Maximizing Scientific and Regulatory Clarity for the Biosimilar Product Development Community

Maximizing scientific and regulatory clarity for the biosimilar product development community was the focus of Key Area 2. Timely guidance and communication to sponsors can help facilitate scientific and regulatory predictability. A tabular listing of the priority deliverables and the notable accomplishments associated with Key Area 2 are included in Table 2.

Table 2. Key Area 2 Priority Deliverables and Notable Accomplishments

Priority Deliverable	Notable Accomplishments
Increase regulatory certainty for stakeholders by focusing efforts on the rapid development of additional guidance to provide further clarification of the regulatory pathway for biosimilar and interchangeable biosimilar products. Add to the existing body of published FDA guidance on biosimilars, interchangeable biosimilars, and other aspects of the BPCI Act. Hold public meetings and hearings to seek additional input on possible alternative approaches.	FDA held two public hearings: • "Facilitating Competition and Innovation in the Biological Products Marketplace" public hearing[6] in September 2018. • "The Future of Insulin Biosimilars: Increasing Access and Facilitating the Efficient Development of Biosimilar and Interchangeable Insulin Products" public hearing[7] in May 2019. The public docket for September 2018[8] and May 2019[9] includes feedback gained from audience during the public hearings. FDA developed and published several final and draft guidances.[10] These include: • Final Guidance: Labeling for Biosimilar Products, published in July 2018. • Final Guidance: Interpretation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009, published in December 2018. • Final Guidance: The "Deemed to be a License" Provision of the BPCI Act: Questions and Answers, published in March 2020. • Final Guidance: Considerations in Demonstrating Interchangeability with a Reference Product, published in May 2019. • Draft Guidance: Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations Guidance for Industry, published in May 2019. • Draft Guidance: Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products, published in November 2019.

[6] Facilitating Price Competition and Innovation in the Biological Products Marketplace Public Hearing: https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/facilitating-price-competition-and-innovation-biological-products-marketplace-public-hearing

[7] The Future of Insulin Biosimilars: Increasing Access and Facilitating the Efficient Development of Biosimilar and Interchangeable Insulin Products: https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/future-insulin-biosimilars-increasing-access-and-facilitating-efficient-development-biosimilar-and

[8] September 2018 Public Docket: https://www.regulations.gov/docket/FDA-2018-N-2689

[9] May 2019 Public Docket: https://www.regulations.gov/docket/FDA-2019-N-1132

[10] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents. Draft guidances will represent the FDA's current thinking on a topic once finalized.

Priority Deliverable	Notable Accomplishments
	• Draft Guidance: Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act, published November 2020.[11] • Draft Guidance: Questions and Answers on Biosimilar Development and the BPCI Act Guidance for Industry, published September 2021. • Draft Guidance: New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 3), published September 2021.
Develop updated guidance to provide additional clarity to biosimilar applicants who seek approval for fewer than all conditions of use for which the reference product is licensed.	FDA published a draft guidance in February 2020 titled "Biosimilars and Interchangeable Biosimilars: Licensure for Fewer Than All Conditions of Use for Which the Reference Product Has Been Licensed Guidance for Industry."[12]
Develop a proposed rule on the interpretation of the definition of "biological product" in the BPCI Act, which would provide additional clarity and predictability for sponsors regarding the appropriate review pathway for such products.	FDA published a proposed rule[13] in December 2018 and a final rule[14] in February 2020 on the definition of the term "biological product" in the BPCI Act.
Improve regulatory clarity by evaluating its regulations regarding the submission and review of BLAs to ensure that they account for current practices and authorities.	FDA evaluated its regulations regarding the submission and review of BLAs to ensure that they account for current practices and authorities.
Provide timely, easy-to-use information about approved biological products, including biosimilar and interchangeable biosimilar products, by developing an enhanced purple book.	FDA published the modernized the Purple Book in February 2020. FDA released the updated Purple Book database in three phases to allow for modifications based on public comment and user testing. This phased release was completed in August 2020 with the final version consisting of product-specific and exclusivity information for biological products. Specifically, the Purple Book database contains information about all FDA-licensed biological products regulated by CDER, including licensed biosimilar and interchangeable biosimilar products, and their reference products. The Purple Book also contains information about all FDA-licensed allergenic, cellular and gene therapy, hematologic, and vaccine products regulated by CBER. In June 2021, FDA updated the Purple Book to include patent information provided to FDA by reference product sponsors for certain licensed biological products in compliance with the Biological Product Patent Transparency section of the Consolidated Appropriations Act, 2021.

[11] Check for the revised version September 2023 at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biosimilarity-and-interchangeability-additional-draft-qas-biosimilar-development-and-bpci-act
[12] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents. Draft guidances will represent the FDA's current thinking on a topic once finalized.
[13] 83 Fed. Reg. 63817, Proposed Rule – Definition of the Term "Biological Product": https://www.federalregister.gov/documents/2018/12/12/2018-26840/definition-of-the-term-biological-product
[14] 85 Fed. Reg. 10057, Final Rule – Definition of the Term "Biological Product": https://www.federalregister.gov/documents/2020/02/21/2020-03505/definition-of-the-term-biological-product

Priority Deliverable	Notable Accomplishments
Continue to publish information about newly approved or withdrawn BLAs and about reference produce exclusivity determinations.	In 2023, FDA included marketing status information for biological products with increased accuracy due to new reporting requirements for BLA holders. These reporting requirements for BLA holders were added in the Consolidated Appropriations Act, 2023, which amended section 506I of the Federal Food, Drug, and Cosmetic Act to require prompt reports of marketing status for biological products.
Strengthen FDA's partnerships with regulatory authorities in Europe, Japan, and Canada and support an efficient global market for biosimilars.	FDA, in partnership with international regulatory authorities, assisted in the publishing of the International Coalition of Medicines Regulatory Authorities (ICMRA) statement about confidence in biosimilar products (for patients and the public)[15] and the ICMRA statement about confidence in biosimilar products (for healthcare professionals),[16] both in July 2019. FDA is an active participant and currently co-chairs the International Pharmaceutical Regulators Programme (IPRP) Biosimilars Working Group[17] as well as the Biosimilar Cluster. The Biosimilar Cluster continues to meet quarterly, as needed.
Utilize real-world evidence to support safety assessments and appropriate prescribing of biosimilars by gathering data across several of FDA's current data sources, including FDA adverse event reporting system (FAERS) and sentinel, and through partnerships with private insurers and the Centers for Medicare and Medicaid Services (CMS).	FDA gathered data across several of its current data sources including FAERS and Sentinel, and through partnerships with private insurers and CMS to investigate the use of real-world evidence to support safety assessments and appropriate prescribing of biosimilars. FDA established the Office of Surveillance and Epidemiology (OSE)- Centers for Medicare & Medicaid Services (CMS) Interagency Agreement (IAA) biosimilars sub-project. FDA uses FAERS, Sentinel and insurance partnerships (e.g., coordination facilitated by CMS), to inform safety and prescribing decision-making for biosimilars.

[15] ICMRA statement for patients and the public: http://icmra.info/drupal/sites/default/files/2019-07/ICMRA_statement_about_confidence_in_biosimilar_products_patients_public.pdf
[16] ICMRA statement for healthcare professionals: https://www.icmra.info/drupal/sites/default/files/2019-07/ICMRA_statement_about_confidence_in_biosimilar_product_HCP.PDF
[17] IPRP Biosimilars Working Group: https://www.iprp.global/working-group/biosimilars.

3.3 Key Area 3: Developing Effective Communications to Improve Understanding of Biosimilars Among Patients, Clinicians, and Payors

Developing effective communications to improve understanding of biosimilars among patients, clinicians and payors was the focus of Key Area 3. A tabular listing of the priority deliverables and the notable accomplishments associated with Key Area 3 are included in Table 3.

Table 3. Key Area 3 Priority Deliverables and Notable Accomplishments

Priority Deliverable	Notable Accomplishments
Develop tools to help professional societies and stakeholder organizations share information about biosimilars with additional resources such as a series of videos that explain key concepts.	FDA created a variety of educational materials for patients and stakeholders. FDA: • Released an infographic[18] that provided an overview of key points about biosimilars • Developed a website[19] about biosimilars geared toward patients and other relevant audiences • Created a Consumer Update article "Biosimilar and Interchangeable Biologics: More Treatment Choices"[20] for more information about biologic treatment options • Released the patient infographic[21] and website[22] in Spanish to reach additional audiences FDA released a five-part video[23] series in May 2018 to provide an overview of biosimilar and interchangeable biosimilar products and to highlight key concepts about the development and approval of these products. FDA developed and released a biosimilar curriculum toolkit[24] with a variety of materials targeted for different healthcare audiences intended to educate students in healthcare professional degree programs for nursing, medicine, physician associates, and pharmacy. FDA also created three updated fact sheets for Healthcare Providers to learn more about biosimilar products, interchangeable biological products, and the approval process, which were released in July 2021. These included: • Overview of Biosimilar Products[25] • Biosimilar Regulatory Review and Approval[26] • Interchangeable Biological Products[27]

[18] Biosimilars Basics infographic: https://www.fda.gov/media/130918/download
[19] Biosimilars website: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars
[20] Biosimilar and Interchangeable Biologics: More Treatment Choices: https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices
[21] Patient infographic in Spanish: https://www.fda.gov/media/142497/download
[22] Biosimilar website in Spanish: https://www.fda.gov/drugs/biosimilars/conceptos-basicos-de-los-biosimilares-para-los-pacientes
[23] Video Series about Biosimilar and Interchangeable Products: https://www.fda.gov/drugs/drug-safety-and-availability/fda-video-series-about-biosimilar-and-interchangeable-products
[24] Biosimilar Curriculum Toolkit: https://www.fda.gov/drugs/biosimilars/curriculum-materials-health-care-degree-programs-biosimilars
[25] Overview of Biosimilar Products: https://www.fda.gov/media/151058/download
[26] Biosimilar Regulatory Review and Approval: https://www.fda.gov/media/151061/download
[27] Interchangeable Biological Products: https://www.fda.gov/media/151094/download

Priority Deliverable	Notable Accomplishments
	From 2017 to 2021, FDA released three webinars for Continuing Education Credit (CE) for pharmacists, nurses, and doctors with topics discussing: • Overview of the Regulatory Framework and the Development and Approval of Biosimilar Products in the U.S.[28] • Scientific Concepts, Clinical Use, and Practical Considerations.[29] • An Updated Review of Scientific Concepts and Practical Resources.[30]
Host additional webinars on topics of interest identified by stakeholders and FDA to increase understanding about biosimilar and interchangeable biosimilar medications among payors and other stakeholders.	FDA held several webinars with audiences that included America's Health Insurance Plans (AHIP), BF Employer Stakeholder, BF Payor, and others. The goal was to emphasize the rigor of the development and approval process.
Engage stakeholders by addressing knowledge gaps and encourage stakeholder use of FDA biosimilars webpages and resources.	FDA provides ongoing technical assistance on publications about biosimilars for stakeholder organizations. FDA participated in multiple events such as podcasts, workshops, webinars, and forums to engage and encourage dialogue about biosimilars, to address knowledge gaps that healthcare professional, patient and other stakeholders have, and to encourage the use of FDA developed resources on biosimilars. FDA conducted a Reddit Ask Me Anything in 2018 to specifically engage pharmacists through the Reddit r/Pharmacy forum to address their questions on biosimilars and interchangeable products.

[28] An Overview of the Regulatory Framework and the Development and Approval of Biosimilar Products in the U.S.: https://www.fda.gov/drugs/biosimilars/fda-webinar-overview-regulatory-framework-and-fdas-guidance-development-and-approval-biosimilar-and

[29] The Scientific Concepts, Clinical Use, and Practical Considerations: https://www.fda.gov/about-fda/fda-drug-topics-biosimilar-and-interchangeable-products-us-scientific-concepts-clinical-use-and

[30] An Updated Review of Scientific Concepts and Practical Resources: https://www.fda.gov/about-fda/fda-pharmacy-student-experiential-program/biosimilar-and-interchangeable-biological-products-updated-review-scientific-concepts-and-practical

3.4 Key Area 4: Supporting Market Competition by Reducing Gaming of FDA Requirements or Other Attempts to Unfairly Delay Competition

Supporting market competition for biological products is the focus of Key Area 4. A tabular listing of the priority deliverables and the notable accomplishments associated with Key Area 4 are included in Table 4.

Table 4. Key Area 4 Priority Deliverables and Notable Accomplishments

Priority Deliverable	Notable Accomplishments
Clarify our position on issues affecting reference product exclusivity to better effectuate balance between innovation and competition. take action to reduce gaming of FDA requirements and coordinate with the FTC to address anti-competitive behavior. Work with legislators, as needed, to close any loopholes that may effectively delay biosimilar competition beyond the exclusivity periods envisioned by congress.	FDA announced a joint statement[31] with FTC and held a workshop on March 9, 2020, entitled: "Public Workshop: FDA/FTC Workshop on a Competitive Marketplace for Biosimilars."[32] A workshop report was also published in March 2023. FDA published Draft Guidance: Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products: Q&A (February 2020).[33] FDA published Final Guidance: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (September 2019).
Applying the same principles used in the Drug Competition Action Plan (DCAP) to the BAP to address circumstances in which drug makers refuse to sell samples, or use any other anticompetitive strategies, to delay the entry of biosimilar or interchangeable biosimilar development and competition.	The CREATES Act, the law widely known as CREATES, was enacted in December 2019 as part of the Further Consolidated Appropriations Act of 2020. This law makes available a pathway for developers of potential drug and biological products to obtain samples of brand products[34] that they need to support their applications.[35] FDA published Draft Guidance: How To Obtain a Covered Product Authorization (September 2022).[36]

3.5 Key Actions

The 2018 BAP also included a section of key actions that relate to the goals outlined in the BAP but were listed separately. This table lists the 11 key actions that supported FDA's commitment to encouraging innovation and competition among biologics and the development of biosimilars. Table 5 outlines how each of the 11 Key Actions relate to each of the Key Areas 1-4.

[31] U.S. Food & Drug Admin. & Fed. Trade Comm'n, Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace (2020): https://www.fda.gov/media/134864/download

[32] Public Workshop: FDA/FTC Workshop on a Competitive Marketplace for Biosimilars: https://www.fda.gov/drugs/news-events-human-drugs/public-workshop-fdaftc-workshop-competitive-marketplace-biosimilars-03092020

[33] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[34] For the purposes of this summary, the term "brand products" refers to products approved under sections 505(b) or (j) of the Federal Food, Drug and Cosmetic Act or sections 351(a) or (k) of the Public Health Service Act.

[35] https://www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act#:~:text=CREATES%20establishes%20a%20private%20right,needed%20to%20support%20their%20applications.

[36] FDA Draft Guidance: How to Obtain a Covered Product Authorization (September 2022): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-obtain-covered-product-authorization

Table 5. Description and Cross-Cutting Alignment of Key Actions to Key Areas 1-4

Key Action	Description	Key Area 1	Key Area 2	Key Area 3	Key Area 4
1	Developing and implementing new FDA review tools, such as standardized review templates that are tailored to marketing applications for biosimilar and interchangeable products, to improve the efficiency of FDA review and enhance the public information about FDA's evaluation of these products.	✓			
2	Creating information resources and development tools for sponsors of biosimilar applications. This includes tools such as in silico models and simulations to correlate pharmacokinetic and pharmacodynamic responses with clinical performance. Such tools can make biosimilar drug development more efficient.	✓	✓		
3	Enhancing the Purple Book to include more information about approved biological products, including information relating to reference product exclusivity determinations.		✓		
4	Actively exploring the potential for entering into new data sharing agreements with foreign regulators to facilitate the increased use of non-U.S.-licensed comparator products in certain studies to support a biosimilar application.		✓		
5	Establishing OTBB to improve coordination and support of activities under the BsUFA program, accelerate responses to stakeholders and support efficient operations and policy development.	✓			
6	Building on the FDA's Biosimilar Education and Outreach Campaign, continue providing critical education to health care professionals, including releasing a series of videos that explain key concepts about biosimilar and interchangeable products.			✓	
7	Publishing final or revised draft guidance on biosimilar product labeling to assist sponsors in determining what data and information should be included in the labeling.		✓		
8	Providing additional clarity for product developers on demonstrating interchangeability, including by publishing final or revised draft guidance.		✓		
9	Providing additional clarity and flexibility for product developers on analytical approaches to evaluating product structure and function to support a demonstration of biosimilarity, including by publishing revised draft guidance on the use of data analysis methods, including statistical approaches.		✓		
10	Providing additional support for product developers regarding product quality and manufacturing process, including by identifying physical product quality attributes that are most critical to evaluate, and by exploring ways to reduce the number of lots of the reference product required for testing.		✓		
11	Engaging in a public dialogue through a Part 15 hearing and opening a docket to request additional information from the public on what additional policy steps the FDA should consider as we seek to enhance our biosimilar program.		✓		

4. CONCLUSION

Biosimilars will continue to be a priority for FDA and we will continue the efforts started in the 2018 BAP with an updated BAP in 2024. The updated BAP will continue relevant activities and efforts and add new aims to further support implementation efforts and better inform regulatory decision-making.

The FDA's 2018 BAP focused the Agency's activities on four key areas that could make the most impact: (1) improving the efficiency of the biosimilar and interchangeable product development and approval process; (2) maximizing scientific and regulatory clarity for the biosimilar product development community; (3) developing effective communications to improve understanding of biosimilars among patients, clinicians, and payors; and (4) supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay competition.

The intended impact of these activities is to further enhance and facilitate the review and approval of biosimilar and interchangeable biosimilar products in the United States, to encourage innovation and competition for biologics, and to meet one of FDA's public health goals—that patients have access to safe and effective biological treatment options at potentially lower cost.

Within all key areas, FDA completed activities that improved the efficiency, transparency, and consistency of the process for reviewing and approving biosimilar and interchangeable biosimilar products. FDA also enhanced the dissemination of information, further supporting the development of these products. Furthermore, FDA completed activities that improved communication with professional, industry, and public stakeholders to provide regulatory clarity and to increase accurate, unbiased information about biosimilars.

To continue the momentum gained while implementing the 2018 BAP, FDA is updating and modernizing the BAP into a web-based format. New activities will be added and activities from the 2018 BAP will be continued as part of the efforts outlined in the updated BAP. These activities generally include developing and revising guidance documents, strengthening partnerships with international regulatory authorities, developing communications to support education and outreach, and continuing enhancements to the Purple Book. Visit the FDA website[37] for more details about the updated BAP.

[37] FDA Website: https://www.fda.gov/drugs/biosimilars/biological-product-innovation-and-competition

5. APPENDIX: ACRONYMS

This section includes a definition for all acronyms used in this document.

ACRONYM	DEFINITION
BAP	Biosimilar Action Plan
BLA	Biologics License Applications
BMER	Biosimilar Multidisciplinary Evaluation and Review
BPCI Act	Biologics Price Competition Innovation Act of 2009
BsUFA	Biosimilar User Fee Act
CAA	Comparative Analytical Assessments
CDER	Center for Drug Evaluation and Research
CE	Continuing education
CEU	Continuing education units
CMC	Chemistry, manufacturing, and controls
DARS	Division of Applied Regulatory Science
DCAP	Drug Competition Action Plan
FAERS	FDA Adverse Event Reporting System
FDA	Food and Drug Administration
FTC	Federal Trade Commission
HELP	Health, Education, Labor and Pension
HHS	Health and Human Services
ICMRA	International Coalition of Medicines Regulatory Authorities
IPRP	International Pharmaceutical Regulators Programme
OB	Office of Biostatistics
OBP	Office of Biotechnology Products
OCC	Office of the Chief Counsel
OCP	Office of Combination Products
OMB	Office of Management and Budget
OND	Office of New Drugs
OPLIA	Office of Policy, Legislation, and International Affairs
OTBB	Office of Therapeutic Biologics and Biosimilars
PHS	Public Health Service
Q&A	Question and Answer
TBBS	Therapeutic Biologics and Biosimilars Staff
TBP	Therapeutic Biologics Program
USP	United States Pharmacopeia