

119TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

To improve the inspections of drug establishments engaged in the manufacture, preparation, propagation, or processing of biosimilar biological products conducted by the Food and Drug Administration, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

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Mr. BUDD (for himself and Ms. HASSAN) introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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**A BILL**

To improve the inspections of drug establishments engaged in the manufacture, preparation, propagation, or processing of biosimilar biological products conducted by the Food and Drug Administration, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Biosimilar Inspection  
5 Modernization Act of 2025”.

6 **SEC. 2. DEFINITIONS.**

7 In this Act—

1           (1) the term “biosimilar biological product”  
2 means a biological product licensed under section  
3 351(k) of the Public Health Service Act (42 U.S.C.  
4 262(k));

5           (2) the term “biosimilar biological product es-  
6 tablishment” means an establishment engaged in the  
7 manufacture, preparation, propagation, or proc-  
8 essing of a biosimilar biological product and reg-  
9 istered under subsection (b)(1), (c)(1), or (i) of sec-  
10 tion 510 of the Federal Food, Drug, and Cosmetic  
11 Act (21 U.S.C. 360); and

12           (3) the term “Secretary” means the Secretary  
13 of Health and Human Services, acting through the  
14 Commissioner of Food and Drugs.

15 **SEC. 3. PUBLIC MEETING AND REPORT ON MUTUAL REC-**  
16 **OGNITION AGREEMENTS.**

17           (a) PUBLIC MEETING.—Not later than 180 days  
18 after the date of enactment of this Act, the Secretary shall  
19 conduct a public meeting on the use of mutual recognition  
20 agreements for purposes of carrying out inspections under  
21 section 704 of the Federal Food, Drug, and Cosmetic Act  
22 (21 U.S.C. 374) of establishments engaged in the manu-  
23 facture, preparation, propagation, or processing of a bio-  
24 similar biological product, including a discussion of—

1           (1) how mutual recognition agreements are uti-  
2           lized with respect to the inspection of biosimilar bio-  
3           logical product establishments, and areas for im-  
4           provements in such inspections conducted pursuant  
5           to such agreements; and

6           (2) areas in which use of mutual recognition  
7           agreements could be expanded to apply beyond com-  
8           pliance inspections under section 704 of the Federal  
9           Food, Drug, and Cosmetic Act (21 U.S.C. 374), in-  
10          cluding for use in conjunction with remote regu-  
11          latory assessments, inspections conducted by trusted  
12          foreign partners identified by the Food and Drug  
13          Administration, and virtual interactions with subject  
14          matter experts.

15          (b) REPORT.—Not later than 180 days after the pub-  
16          lic meeting under subsection (a) is conducted, the Sec-  
17          retary shall issue to the Committee on Health, Education,  
18          Labor, and Pensions of the Senate and the Committee on  
19          Energy and Commerce of the House of Representatives,  
20          and make publicly available, a report that includes rec-  
21          ommendations on the use of mutual recognition agree-  
22          ments for purposes of conducting inspections of biosimilar  
23          biological product establishments.

1 **SEC. 4. ENSURING FLEXIBILITY IN INSPECTION TOOLS.**

2 The Secretary shall update inspection processes and  
3 existing tools to advance a risk-based approach to evalu-  
4 ate, including conducting inspections, of establishments  
5 engaged in the manufacture, preparation, propagation, or  
6 processing of biosimilar biological products to enable the  
7 Food and Drug Administration to—

8 (1) increase utilization of remote regulatory as-  
9 sessments under section 704 of the Federal Food,  
10 Drug, and Cosmetic Act (21 U.S.C. 374), in accord-  
11 ance with the guidance issued by the Food and Drug  
12 Administration, titled “Conducting Remote Regu-  
13 latory Assessments—Questions and Answers” (June  
14 24, 2025) (or any successor guidance); and

15 (2) maximize the use of alternative tools set  
16 forth in the guidance described in paragraph (1) to  
17 improve inspection efficiency.

18 **SEC. 5. FDA STRATEGIC PLAN ON DOMESTIC INSPECTION**  
19 **IMPROVEMENTS FOR BIOSIMILAR BIOLOGI-**  
20 **CAL FACILITIES.**

21 Not later than 1 year after the date of enactment  
22 of this Act, the Secretary shall develop and publish a stra-  
23 tegic plan on ways the Food and Drug Administration will  
24 address challenges with respect to the inspection of domes-  
25 tic biosimilar biological product establishments, including  
26 regarding—

- 1           (1) recruiting and retaining inspections staff;
- 2           (2) challenges specific to inspecting domestic
- 3           biosimilar biological product establishments;
- 4           (3) improving internal communication among
- 5           all Food and Drug Administration personnel in-
- 6           volved in inspections of biosimilar biological product
- 7           establishments; and
- 8           (4) expanding opportunities for external com-
- 9           munications with sponsors of applications under sec-
- 10          tion 351(k) of the Public Health Service Act (42
- 11          U.S.C. 262(k)), including informing such sponsors
- 12          about potential inspection requirements and resolv-
- 13          ing outstanding inspection related questions earlier
- 14          in the review process.