

119TH CONGRESS
1ST SESSION

H. R. 5791

To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to establish an expedited process for the approval of certain biologics license application supplements for blood centers, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 17, 2025

Mr. WIED (for himself, Ms. SCHRIER, and Mr. TIFFANY) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to establish an expedited process for the approval of certain biologics license application supplements for blood centers, 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 “Boosting Lifesaving
5 Operations, Opening Donation Centers Act” or the
6 “BLOOD Centers Act”.

1 **SEC. 2. EXPEDITED PROCESS FOR APPROVAL OF CERTAIN**
2 **BLA SUPPLEMENTS FOR BLOOD CENTERS.**

3 (a) ESTABLISHMENT.—Not later than 180 days after
4 the date of enactment of this Act, the Secretary, acting
5 pursuant to section 351(a)(2) of the Public Health Service
6 Act (42 U.S.C. 262(a)(2)), shall establish an expedited
7 process for the approval of a supplemental application sub-
8 mitted by the owner or operator of a blood center seeking
9 to add an apheresis collection device to an existing BLA
10 license at a location not previously licensed for such a de-
11 vice.

12 (b) DEADLINE.—Under the expedited procedure, the
13 Secretary shall approve a supplemental application de-
14 scribed in subsection (a) not later than 30 days after the
15 date of submission of the application unless the Secretary
16 makes a showing that there is—

17 (1) a specific concern for the safety, purity, or
18 potency of products produced at the specific location
19 subject to the supplemental application; or

20 (2) a systemic failure by the owner or operator
21 to meet standards designed to ensure the continued
22 safety, purity, and potency of products produced at
23 other locations under a biologics license.

24 (c) APPLICABILITY.—The expedited procedure shall
25 apply with respect to a supplemental application described

1 in subsection (a) if the owner or operator that submits
2 the application—

3 (1) holds a biologics license for at least one
4 blood center site; and

5 (2)(A) has been approved for a biologics license
6 at 3 or more Food and Drug Administration reg-
7 istered locations under the biologics license referred
8 to in paragraph (1); or

9 (B) is accredited and in good standing for blood
10 collection by an accreditation organization with
11 standards that meet or exceed, as determined by the
12 Secretary, all applicable regulatory requirements for
13 blood collections.

14 (d) DEFINITIONS.—In this section:

15 (1) BLA.—The term “BLA” means a biologics
16 license application.

17 (2) BLOOD CENTER.—The term “blood center”
18 means a human blood donation center.

19 (3) EXPEDITED PROCEDURE.—The term “expe-
20 dited procedure” means the expedited procedure to
21 be established under subsection (a).

22 (4) SECRETARY.—The term “Secretary” means
23 the Secretary of Health and Human Services acting
24 through the Commissioner of Food and Drugs.

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