

119TH CONGRESS  
2D SESSION

# H. R. 7693

To mitigate the effects of the COVID–19 pandemic on incentives under the Federal Food, Drug, and Cosmetic Act for the development of orphan drugs, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 25, 2026

Mr. GOTTHEIMER (for himself and Mr. BACON) introduced the following bill;  
which was referred to the Committee on Energy and Commerce

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## A BILL

To mitigate the effects of the COVID–19 pandemic on incentives under the Federal Food, Drug, and Cosmetic Act for the development of orphan drugs, 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 “Leo’s Law”.

1 **SEC. 2. MITIGATION OF EFFECTS OF COVID-19 PANDEMIC**  
2 **ON ORPHAN-DRUG DEVELOPMENT INCEN-**  
3 **TIVES.**

4 (a) IN GENERAL.—In the case of a covered orphan  
5 drug, each of the following exclusivity periods is deemed  
6 to be extended by 180 days, so long as such period is not  
7 expired:

8 (1) The 12-year period referred to in subpara-  
9 graph (A) of section 351(k)(7) of the Public Health  
10 Service Act (42 U.S.C. 262(k)(7)).

11 (2) The 5-year period referred to in subsection  
12 (c)(3)(E)(ii) and subsection (j)(5)(F)(ii) of section  
13 505 of the Federal Food, Drug, and Cosmetic Act  
14 (21 U.S.C. 355).

15 (3) The 3-year period referred to in each of  
16 clauses (iii) and (iv) of subsection (c)(3)(E) and  
17 clauses (iii) and (iv) of subsection (j)(5)(F) of sec-  
18 tion 505 of the Federal Food, Drug, and Cosmetic  
19 Act (21 U.S.C. 355).

20 (4) The 7-year period referred to in section  
21 527(a) of the Federal, Food, Drug, and Cosmetic  
22 Act (21 U.S.C. 360cc).

23 (5) In the case of a covered orphan drug with  
24 one or more certifications specified in clauses (ii),  
25 (iii), and (iv) of section 505(b)(2)(A) of the Federal  
26 Food, Drug, and Cosmetic Act (21 U.S.C.

1 355(b)(2)(A)), or in subclauses (II), (III), and (IV)  
2 of section 505(j)(2)(A)(vii) of such Act (21 U.S.C.  
3 355(j)(2)(A)(vii)), each corresponding patent-related  
4 approval-delay period (other than a patent for which  
5 the information required pursuant to subsection (b)  
6 or (c) of section 505 of the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 355) has not been filed).

8 (b) CONFORMING EXTENSIONS.—In addition to the  
9 periods extended under subsection (a) for a covered or-  
10 phan drug, the following periods are each deemed to be  
11 extended by 180 days:

12 (1) The 4-year period referred to in subpara-  
13 graph (B) of section 351(k)(7) of the Public Health  
14 Service Act (42 U.S.C. 262(k)(7)).

15 (2) The 4-year, 48-month, and 7 and one-half-  
16 year periods referred to in subsection (c)(3)(E)(ii)  
17 and subsection (j)(5)(F)(ii) of section 505 of the  
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
19 355).

20 (c) DEFINITIONS.—In this section:

21 (1) The term “covered orphan drug” means an  
22 orphan drug for which—

23 (A) an application is submitted under sec-  
24 tion 505(i) of the Federal Food, Drug, and  
25 Cosmetic Act (21 U.S.C. 355(i)) during the

1 COVID–19 emergency period (without regard  
2 to whether the same applicant has submitted  
3 such application for the same drug before De-  
4 cember 1, 2019, for a different rare disease or  
5 condition);

6 (B) an application under section 505(b) of  
7 the Federal Food, Drug, and Cosmetic Act or  
8 under section 351(a) of the Public Health Serv-  
9 ice Act (or a supplemental application, as the  
10 case may be) is approved pursuant to the inves-  
11 tigational new drug application referred to in  
12 paragraph (1); and

13 (C) there is no approved indication that is  
14 not for a rare disease or condition.

15 (2) The term “corresponding patent-related ap-  
16 proval delay period”, with respect to a covered or-  
17 phan drug, means the period ending with the last  
18 applicable date for the approval of an application  
19 within the meaning of subparagraph (A), (B), or (C)  
20 of section 505(c)(3) of the Federal, Food, Drug, and  
21 Cosmetic Act (21 U.S.C. 355(c)(3)), or clause (i),  
22 (ii), or (iii) of section 505(j)(5)(B) of such Act (21  
23 U.S.C. 355(j)(5)(B)), whichever applies pursuant to  
24 the applicable patent certification.

1           (3) The term “orphan drug” means a drug that  
2           the Secretary has designated as a drug for a rare  
3           disease or condition under section 526(a) of the  
4           Federal, Food, Drug, and Cosmetic Act (21 U.S.C.  
5           360bb(a)).

6           (4) The term “COVID–19 emergency period”  
7           means the period beginning on December 1, 2019,  
8           and ending on the date that is not later than 120  
9           days before the date on which the emergency period  
10          (as defined in section 1135(g)(1)(B) of the Social  
11          Security Act (42 U.S.C. 1320b–5(g)(1)(B))) termi-  
12          nates.

13          (5) The term “rare disease or condition” has  
14          the meaning given such term in section 526 of the  
15          Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
16          360bb).

17          (d) EFFECTIVE DATE.—This section takes effect  
18          upon the date of the enactment of this Act, without regard  
19          to whether the Secretary has issued guidance or regula-  
20          tions regarding the implementation of this Act.

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