

116TH CONGRESS
2D SESSION

H. R. 4712

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act with respect to limitations on exclusive approval or licensure 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Fairness in Orphan
3 Drug Exclusivity Act”.

4 **SEC. 2. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICEN-**
5 **SURE OF ORPHAN DRUGS.**

6 (a) IN GENERAL.—Section 527 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

8 (1) in subsection (a), by striking “Except as
9 provided in subsection (b)” and inserting “Except as
10 provided in subsection (b) or (f)”; and

11 (2) by adding at the end the following:

12 “(f) LIMITATIONS ON EXCLUSIVE APPROVAL, CER-
13 TIFICATION, OR LICENSE.—

14 “(1) IN GENERAL.—For a drug designated
15 under section 526 for a rare disease or condition
16 pursuant to the criteria set forth in subsection
17 (a)(2)(B) of such section, the Secretary shall not
18 grant, recognize, or apply exclusive approval or licen-
19 sure under subsection (a), and, if such exclusive ap-
20 proval or licensure has been granted, recognized, or
21 applied, shall revoke such exclusive approval or licen-
22 sure, unless the sponsor of the application for such
23 drug demonstrates—

24 “(A) with respect to an application ap-
25 proved or a license issued after the date of en-
26 actment of this subsection, upon such approval

1 or issuance, that there is no reasonable expecta-
2 tion at the time of such approval or issuance
3 that the cost of developing and making avail-
4 able in the United States such drug for such
5 disease or condition will be recovered from sales
6 in the United States of such drug, taking into
7 account all sales made or reasonably expected
8 to be made within 12 years of first marketing
9 the drug; or

10 “(B) with respect to an application ap-
11 proved or a license issued on or prior to the
12 date of enactment of this subsection, not later
13 than 60 days after such date of enactment, that
14 there was no reasonable expectation at the time
15 of such approval or issuance that the cost of de-
16 veloping and making available in the United
17 States such drug for such disease or condition
18 would be recovered from sales in the United
19 States of such drug, taking into account all
20 sales made or reasonably expected to be made
21 within 12 years of first marketing the drug.

22 “(2) CONSIDERATIONS.—For purposes of sub-
23 paragraphs (A) and (B) of paragraph (1), the Sec-
24 retary and the sponsor of the application for the
25 drug designated for a rare disease or condition de-

1 scribed in such paragraph shall consider sales from
2 all drugs that—

3 “(A) are developed or marketed by the
4 same sponsor or manufacturer of the drug (or
5 a licensor, predecessor in interest, or other re-
6 lated entity to the sponsor or manufacturer);
7 and

8 “(B) are covered by the same designation
9 under section 526.

10 “(3) CRITERIA.—No drug designated under
11 section 526 for a rare disease or condition pursuant
12 to the criteria set forth in subsection (a)(2)(B) of
13 such section shall be eligible for exclusive approval
14 or licensure under this section unless it met such
15 criteria under such subsection on the date on which
16 the drug was approved or licensed.”.

17 (b) RULE OF CONSTRUCTION.—The amendments
18 made in subsection (a) shall apply to any drug that has
19 been or is hereafter designated under section 526 of the
20 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb)
21 for a rare disease or condition pursuant to the criteria
22 under subsection (a)(2)(B) of such section regardless of—

23 (1) the date on which such drug is designated
24 or becomes the subject of a designation request
25 under such section;

1 (2) the date on which such drug is approved
2 under section 505 of such Act (21 U.S.C. 355) or
3 licensed under section 351 of the Public Health
4 Service Act (42 U.S.C. 262) or becomes the subject
5 of an application for such approval or licensure; and

6 (3) the date on which such drug is granted ex-
7 clusive approval or licensure under section 527 of
8 the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 360cc) or becomes the subject of a request
10 for such exclusive approval or licensure.

11 **SEC. 3. DETERMINATION OF BUDGETARY EFFECTS.**

12 The budgetary effects of this Act, for the purpose of
13 complying with the Statutory Pay-As-You-Go Act of 2010,
14 shall be determined by reference to the latest statement
15 titled “Budgetary Effects of PAYGO Legislation” for this
16 Act, submitted for printing in the Congressional Record
17 by the Chairman of the House Budget Committee, pro-
18 vided that such statement has been submitted prior to the
19 vote on passage.

 Passed the House of Representatives November 17,
2020.

Attest:

Clerk.

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