

FAIRNESS IN ORPHAN DRUG EXCLUSIVITY ACT

NOVEMBER 16, 2020.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. PALLONE, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 4712]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4712) 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, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

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

SEC. 2. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICENSURE OF ORPHAN DRUGS.

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

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

(2) by adding at the end the following:

“(f) **LIMITATIONS ON EXCLUSIVE APPROVAL, CERTIFICATION, OR LICENSE.**—

“(1) **IN GENERAL.**—For a drug designated under section 526 for a rare disease or condition pursuant to the criteria set forth in subsection (a)(2)(B) of such section, the Secretary shall not grant, recognize, or apply exclusive approval or licensure under subsection (a), and, if such exclusive approval or licensure has been granted, recognized, or applied, shall revoke such exclusive approval or licensure, unless the sponsor of the application for such drug demonstrates—

“(A) with respect to an application approved or a license issued after the date of enactment of this subsection, upon such approval or issuance, that there is no reasonable expectation at the time of such approval or issuance that the cost of developing and making available in the United States such drug for such disease or condition will be recovered from sales in the United States of such drug, taking into account all sales made or reasonably expected to be made within 12 years of first marketing the drug; or

“(B) with respect to an application approved or a license issued on or prior to the date of enactment of this subsection, not later than 60 days after such date of enactment, that there was no reasonable expectation at the time of such approval or issuance that the cost of developing and making available in the United States such drug for such disease or condition would be recovered from sales in the United States of such drug, taking into account all sales made or reasonably expected to be made within 12 years of first marketing the drug.

“(2) **CONSIDERATIONS.**—For purposes of subparagraphs (A) and (B) of paragraph (1), the Secretary and the sponsor of the application for the drug designated for a rare disease or condition described in such paragraph shall consider sales from all drugs that—

“(A) are developed or marketed by the same sponsor or manufacturer of the drug (or a licensor, predecessor in interest, or other related entity to the sponsor or manufacturer); and

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

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

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

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

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

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

I. PURPOSE AND SUMMARY

H.R. 4712, the “Fairness in Orphan Drug Exclusivity Act”, was introduced by Representatives Madeleine Dean (D-PA), Earl L. “Buddy” Carter (R-GA), Marc A. Veasey (D-TX), and David B. McKinley (R-WV). H.R. 4712 updates the Orphan Drug Act to require drug manufacturers seeking exclusive approval or licensure for an orphan drug designated as such under section 526(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FFDCA) to demonstrate the absence of any reasonable expectation at the time of approval that the costs the manufacturer incurs in developing the

drug will be recovered in the United States within twelve years of first marketing the drug. The bill also requires drug manufacturers with active orphan drug designations under section 526(a)(2)(B) of the FDCA at the time of enactment to make the same demonstration no later than 60 days after enactment and would prohibit a drug from receiving orphan drug exclusivity unless it met the criteria for orphan drug designation on the date that the drug was approved or licensed.

II. BACKGROUND AND NEED FOR LEGISLATION

The Orphan Drug Act was enacted in 1983 to incentivize the development of drugs for rare diseases by providing manufacturers with seven years of exclusive marketing rights from date of approval, during which time the same drug produced by another manufacturer is barred from entering the market.¹ The Orphan Drug Act provides two ways under which the sponsor of a drug application can receive an orphan drug designation: (1) by being approved to treat a disease or condition that affects 200,000 or fewer people, the most commonly used “prevalence” pathway; or (2) if there is no reasonable expectation that the cost of developing a drug and making it available in the United States will be recovered by U.S. sales, the “cost recovery” pathway.² A manufacturer may also receive additional drug exclusivity periods for subsequently approved drugs approved under the same orphan drug designation (i.e. drugs made by the same manufacturer using the same active moiety), regardless of whether the subsequent drugs meet the original requirements of the orphan drug designation. This provision in the law has allowed manufacturers to circumvent the original intent of the Orphan Drug Act and blocked competitors from the market despite evidence that the costs of developing the subsequent drug could be recouped.

An illustrative example of this occurred in 2017, when Sublocade, a buprenorphine drug manufactured by Indivior to treat opioid use disorder, was approved under a 1994 orphan drug designation for Subutex, a similar drug manufactured by Reckitt Benckiser, the former parent company of Indivior.³ Subutex received its orphan drug designation using the cost recovery pathway because, while opioid use disorder affected more than 200,000 people, when the drug was designated as an orphan drug in 1994, it was expected that buprenorphine would only be prescribed in opioid treatment centers, limiting its reach and U.S. sales, ultimately preventing the manufacturer from recovering costs associated with developing the drug and making it available.⁴ Six years later, however, the Drug Addiction Treatment Act of 2000 (DATA 2000) allowed certain qualifying physicians to prescribe buprenorphine outside of opioid treatment programs, expanding access to the drug.⁵ From 2002 to 2011, buprenorphine treatments reached billions of dollars in sales, including \$285 million for Subutex, clearly demonstrating that buprenorphine drugs could generate sufficient sales to recover

¹ Pub. L. No. 97-414.

² 21 U.S.C. § 360bb.

³ Kao-Ping Chua and Rena M. Conti, *Orphan Drugs for Opioid Use Disorder: An Abuse of the Orphan Drug Act*, Health Affairs Blog, <https://www.healthaffairs.org/doi/10.1377/hblog20190724.795814/full/> (July 26, 2019).

⁴ *Id.*

⁵ Enacted as part of the Children’s Health Act of 2000, Pub. L. No. 106-310.

costs.⁶ Subsequent legislation, including the Comprehensive Addiction Recovery Act of 2016 (CARA) again expanded access to buprenorphine, further raising the potential for cost recovery and profitability.⁷ Nevertheless, in 2017, Sublocade, Indivior's follow-on buprenorphine product, was granted orphan drug exclusivity under Subutex's orphan drug designation.⁸ Raising concerns that Sublocade was not a *bona fide* orphan drug (i.e., it did not independently meet the requirements of either of the prevalence or cost recovery pathways, and the drug was intended to serve a large patient population of more than 2 million individuals for which no additional orphan drug incentive was necessary), and an orphan drug exclusivity period would limit competition, Braeburn Inc., a generic drug manufacturer and competitor to Indivior, filed a citizen petition with the Food and Drug Administration (FDA) in 2019, arguing that the agency should revoke the Sublocade's orphan drug designation.⁹ FDA subsequently agreed with portions of the petition and revoked the designation.¹⁰

H.R. 4712 will prevent a similar situation from happening again, allowing for greater competition in the pharmaceutical market and bringing down drug costs, while still preserving the incentives enacted through the Orphan Drug Act to encourage the development of treatments for rare diseases. To do this, the bill prohibits the Secretary of the Department of Health and Human Services (the Secretary) from granting orphan drug exclusivity to drugs seeking designation under the cost recovery pathway, unless the sponsor of the drug application demonstrates that there is no reasonable expectation at the time of approval or licensure that the cost of developing and making the drug available in the United States will be recovered from U.S. sales, taking into account all sales made or reasonably expected to be made within twelve years of first marketing the drug. Additionally, for drugs already approved or licensed, H.R. 4712 requires manufacturers to, no later than 60 days after enactment, demonstrate that at the time of approval, it was not reasonable to expect that costs would be recovered. In the case that exclusive approval or licensure has already been granted, recognized, or applied at the time of enactment, H.R. 4712 would require the Secretary to revoke such exclusivity unless these demonstrations were made. In considering whether an orphan drug applicant has demonstrated the absence of any reasonable expectation at the time of approval that the costs incurred in developing the drug will be recovered, the Secretary would be required to consider the sales of all drugs that are developed or marketed by the same sponsor or manufacturer of the drug, and are covered by the same orphan drug designation. Furthermore, to prevent drugs from receiving unwarranted orphan drug exclusivity based on an earlier drug's orphan drug designation, H.R. 4712 prohibits a drug from

⁶Kao-Ping Chua and Rena M. Conti, *Orphan Drugs for Opioid Use Disorder: An Abuse of the Orphan Drug Act*, Health Affairs Blog, <https://www.healthaffairs.org/doi/10.1377/hblog20190724.795814/full/> (July 26, 2019).

⁷Pub. L. No. 114-198; Pub. L. No. 115-271.

⁸Kao-Ping Chua and Rena M. Conti, *Orphan Drugs for Opioid Use Disorder: An Abuse of the Orphan Drug Act*, Health Affairs Blog, <https://www.healthaffairs.org/doi/10.1377/hblog20190724.795814/full/> (July 26, 2019).

⁹*Citizen Petition Requesting FDA to Revoke Orphan Drug Designation for Sublocade (Buprenorphine Extended-Release) Injection for Treatment of Opiate Addiction in Opiate Users*, Docket No. FDA-2019-P-1697 (April 5, 2019).

¹⁰*Letter from Lowell Schiller, FDA Principal Deputy Commissioner for Policy, to Braeburn Inc. Re: Docket No. FDA-2019-P-1697* (Nov. 7, 2019).

receiving orphan drug exclusivity unless it meets the requirements for orphan drug designation on the day it was approved or licensed. A rule of construction in H.R. 4712 applies these provisions to all drugs receiving an orphan drug designation under the cost recovery pathway regardless of: (1) the date on which it is designated or becomes the subject of a designation request under such section; (2) the date on which it is approved or licensed or the date on which the drug becomes the subject of an application for approval or licensure; and (3) the date on which the drug is granted exclusive approval or licensure, or becomes the subject of an application for approval or licensure.

Although there are no drugs that currently have orphan drug exclusivity under the cost recovery pathway, H.R. 4712 is necessary to prevent unwarranted exclusivity from being granted in the future.

III. COMMITTEE HEARINGS

For the purposes of section 103(i) of H. Res. 6 of the 116th Congress, the following hearing was used to develop or consider H.R. 4712:

The Subcommittee on Health held a legislative hearing on January 29, 2020, entitled, “Improving Safety and Transparency in America’s Food and Drugs.” The hearing focused on H.R. 4712 and related legislation. The Subcommittee received testimony from the following witnesses:

Panel I:

- Jeff Allen, Ph.D., President and CEO, Friends of Cancer Research
- Richard Kaeser, Vice President, Global Brand Protection, Johnson & Johnson
- Fernando Muzzio, Ph.D., Distinguished Professor, Chemical and Biochemical Engineering, Rutgers, the State University of New Jersey
- Kao-Ping Chua, M.D., Ph.D., Assistant Professor, Department of Pediatrics, University of Michigan Medical School

Panel II:

- Melanie Benesh, Legislative Attorney, Environmental Working Group
- Tom Balmer, Executive Vice President, National Milk Producers Federation
- J. David Carlin, Senior Vice President of Legislative Affairs and Economic Policy, International Dairy Foods Association
- Douglas Corey, D.V.M., Past President, American Association of Equine Practitioners
- Talia Day, Patient Advocate
- Paul C. DeLeo, Ph.D., Principal, Integral Consulting, Inc.
- Mardi Mountford, President, Infant Nutrition Council of America
- Nancy Perry, Senior Vice President, Government Relations, American Society for the Prevention of Cruelty to Animals

- Sara Sorscher, Deputy Director of Regulatory Affairs, Center for Science in the Public Interest

IV. COMMITTEE CONSIDERATION

Representatives Dean, Carter (R-GA), Veasey, and McKinley introduced H.R. 4712 on September 26, 2019, and the bill was referred to the Committee on Energy and Commerce. Subsequently, H.R. 4712 was referred to the Subcommittee on Health on September 27, 2019. A legislative hearing was held on the bill on January 29, 2020.

On March 11, 2020, the Subcommittee on Health met in open markup session, pursuant to notice, to consider H.R. 4712. During consideration of the bill, an amendment offered by Ms. Eshoo (D-CA) was agreed to by a voice vote. Subsequently, the Subcommittee on Health agreed to a motion offered by Ms. Eshoo, Chairwoman of the subcommittee, to forward favorably H.R. 4712, amended, to the full Committee on Energy and Commerce by a voice vote.

On July 15, 2020, the full Committee met in virtual open markup session, pursuant to notice, to consider a committee print of the bill H.R. 4712, as amended by the Subcommittee on Health on March 11, 2020. During consideration of the bill, a manager's amendment offered by Mr. Veasey was agreed to by a voice vote. Upon conclusion of consideration of the bill, the full Committee agreed to a motion on final passage offered by Mr. Pallone, Chairman of the committee, to order H.R. 4712 reported favorably to the House, amended, by a voice vote, a quorum being present.

V. COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that there were no record votes taken on H.R. 4712, including the motion for final passage of the bill.

VI. OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

VII. NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

VIII. FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

IX. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to amend the Federal Food, Drug, and Cosmetic Act with respect to limitations on exclusive approval or licensure of orphan drugs.

X. DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 4712 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111-139 or the most recent Catalog of Federal Domestic Assistance.

XI. COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

XII. EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 4712 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIII. ADVISORY COMMITTEE STATEMENT

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

XIV. APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

XV. SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that the short title may be cited as the "Fairness in Orphan Drug Exclusivity Act".

Sec. 2. Limitations on exclusive approval or licensure of orphan drugs

Section 2(a) states that under section 527 of the FFDCA the Secretary may not grant, recognize, or apply orphan drug exclusivity unless the sponsor of the drug application demonstrates that there is no reasonable expectation at the time of approval that the manufacturer would recover costs incurred in developing or making the

drug available in the United States through sales within the United States within the first twelve years of marketing the drug. In the case of a drug for which exclusivity has been granted, recognized, or applied prior to enactment, this section requires that the Secretary revoke such exclusivity unless the manufacturer can make the same demonstration within 60 days of enactment. When making determinations regarding the sales of drugs and the ability to recover costs, the Secretary would be required under section 2 to consider all drugs that are developed by the same sponsor or manufacturer of the drug (or a licensor, predecessor in interest, or other related entity to the sponsor or manufacturer) that are covered under the same orphan drug designation under section 526 of the FFDCA.

Section 2(a) also states that no drug receiving orphan drug designation under section 526(a)(2)(B) (the “cost recovery” pathway) of the FFDCA shall be eligible for orphan drug exclusivity unless it met the criteria of section 526(a)(2)(B) on the date it was approved or licensed.

Finally, section 2(b) includes a rule of construction applying the provisions of section 2(a) to any drug that has been or will in the future be designated under section 526(a)(2)(B) of the FFDCA, regardless of—(1) the date on which a drug is designated or becomes the subject of a designation request under section 526; (2) the date on which a drug is approved under section 505 of the FFDCA, licensed under section 351 of the Public Health Service Act or becomes the subject of an application for such approval or licensure; and (3) the date on which a drug is granted exclusive approval or licensure under section 527 of the FFDCA or becomes the subject of a request for such exclusive approval or licensure.

XVI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER V—DRUGS AND DEVICES

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SUBCHAPTER B—DRUGS FOR RARE DISEASES OR CONDITIONS

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PROTECTION FOR DRUGS FOR RARE DISEASES OR CONDITIONS

SEC. 527. (a) **【**Except as provided in subsection (b)**】** *Except as provided in subsection (b) or (f), if the Secretary—*

- (1) approves an application filed pursuant to section 505, or
- (2) issues a license under section 351 of the Public Health Service Act

for a drug designated under section 526 for a rare disease or condition, the Secretary may not approve another application under section 505 or issue another license under section 351 of the Public Health Service Act for the same drug for the same disease or condition for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of the approval of the approved application or the issuance of the license. Section 505(c)(2) does not apply to the refusal to approve an application under the preceding sentence.

(b) During the 7-year period described in subsection (a) for an approved application under section 505 or license under section 351 of the Public Health Service Act, the Secretary may approve an application or issue a license for a drug that is otherwise the same, as determined by the Secretary, as the already approved drug for the same rare disease or condition if—

(1) the Secretary finds, after providing the holder of exclusive approval or licensure notice and opportunity for the submission of views, that during such period the holder of the exclusive approval or licensure cannot ensure the availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated; or

(2) the holder provides the Secretary in writing the consent of such holder for the approval of other applications or the issuance of other licenses before the expiration of such seven-year period.

(c) **CONDITION OF CLINICAL SUPERIORITY.**—

(1) **IN GENERAL.**—If a sponsor of a drug that is designated under section 526 and is otherwise the same, as determined by the Secretary, as an already approved or licensed drug is seeking exclusive approval or exclusive licensure described in subsection (a) for the same rare disease or condition as the already approved drug, the Secretary shall require such sponsor, as a condition of such exclusive approval or licensure, to demonstrate that such drug is clinically superior to any already approved or licensed drug that is the same drug.

(2) **DEFINITION.**—For purposes of paragraph (1), the term “clinically superior” with respect to a drug means that the drug provides a significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care.

(d) **REGULATIONS.**—The Secretary may promulgate regulations for the implementation of subsection (c). Beginning on the date of enactment of the FDA Reauthorization Act of 2017, until such time as the Secretary promulgates regulations in accordance with this subsection, the Secretary may apply any definitions set forth in regulations that were promulgated prior to such date of enactment, to the extent such definitions are not inconsistent with the terms of this section, as amended by such Act.

(e) **DEMONSTRATION OF CLINICAL SUPERIORITY STANDARD.**—To assist sponsors in demonstrating clinical superiority as described in subsection (c), the Secretary—

(1) upon the designation of any drug under section 526, shall notify the sponsor of such drug in writing of the basis for the

designation, including, as applicable, any plausible hypothesis offered by the sponsor and relied upon by the Secretary that the drug is clinically superior to a previously approved drug; and

(2) upon granting exclusive approval or licensure under subsection (a) on the basis of a demonstration of clinical superiority as described in subsection (c), shall publish a summary of the clinical superiority findings.

(f) *LIMITATIONS ON EXCLUSIVE APPROVAL, CERTIFICATION, OR LICENSE.*—

(1) *IN GENERAL.*—For a drug designated under section 526 for a rare disease or condition pursuant to the criteria set forth in subsection (a)(2)(B) of such section, the Secretary shall not grant, recognize, or apply exclusive approval or licensure under subsection (a), and, if such exclusive approval or licensure has been granted, recognized, or applied, shall revoke such exclusive approval or licensure, unless the sponsor of the application for such drug demonstrates—

(A) with respect to an application approved or a license issued after the date of enactment of this subsection, upon such approval or issuance, that there is no reasonable expectation at the time of such approval or issuance that the cost of developing and making available in the United States such drug for such disease or condition will be recovered from sales in the United States of such drug, taking into account all sales made or reasonably expected to be made within 12 years of first marketing the drug; or

(B) with respect to an application approved or a license issued on or prior to the date of enactment of this subsection, not later than 60 days after such date of enactment, that there was no reasonable expectation at the time of such approval or issuance that the cost of developing and making available in the United States such drug for such disease or condition would be recovered from sales in the United States of such drug, taking into account all sales made or reasonably expected to be made within 12 years of first marketing the drug.

(2) *CONSIDERATIONS.*—For purposes of subparagraphs (A) and (B) of paragraph (1), the Secretary and the sponsor of the application for the drug designated for a rare disease or condition described in such paragraph shall consider sales from all drugs that—

(A) are developed or marketed by the same sponsor or manufacturer of the drug (or a licensor, predecessor in interest, or other related entity to the sponsor or manufacturer); and

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

(3) *CRITERIA.*—No drug designated under section 526 for a rare disease or condition pursuant to the criteria set forth in subsection (a)(2)(B) of such section shall be eligible for exclusive approval or licensure under this section unless it met such cri-

teria under such subsection on the date on which the drug was approved or licensed.

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