116TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
116–573

MAKING OBJECTIVE DRUG EVIDENCE REVISIONS FOR NEW LABELING ACT OF 2020

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. 5668]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5668) to amend the Federal Food, Drug, and Cosmetic Act to modernize the labeling of certain generic 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 "Making Objective Drug Evidence Revisions for New Labeling Act of 2020" or the "MODERN Labeling Act of 2020".

SEC. 2. MODERNIZING THE LABELING OF CERTAIN GENERIC DRUGS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503C the following:

"SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN DRUGS.

"(a) DEFINITIONS.—For purposes of this section:

"(1) The term 'covered drug' means a drug approved under section 505(c)—

"(A) for which there are no unexpired patents included in the list under section 505(j)(7) and no unexpired period of exclusivity;

"(B) for which the approval of the application has been withdrawn for reasons other than safety or effectiveness; and

"(C) for which—

"(i)(I) there is new scientific evidence available pertaining to the existing conditions of use that is not reflected in the labeling;

"(II) the approved labeling does not reflect current legal and regulatory requirements for content or format; or

"(III) there is a relevant accepted use in clinical practice that is not reflected in the approved labeling; and

"(ii) updating the labeling would benefit the public health.

"(2) The term 'period of exclusivity', with respect to a drug approved under section 505(c), means any period of exclusivity under clause (ii), (iii), or (iv) of section 505(c)(3)(E), clause (ii), (iii), or (iv) of section 505(j)(5)(F), or section 505A, 505E, or 527.

"(3) The term 'generic version' means a drug approved under section 505(j) whose reference listed drug is a covered drug.

"(4) The term 'relevant accepted use' means a use for a drug in clinical practice that is supported by scientific evidence that appears to the Secretary to meet the standards for approval under section 505.

"(5) The term 'selected drug' means a covered drug for which the Secretary has determined through the process under subsection (c) that the labeling should be changed.

"(b) IDENTIFICATION OF COVERED DRUGS.—The Secretary may identify covered drugs for which labeling updates would provide a public health benefit. To assist in identifying covered drugs, the Secretary may do one or both of the following:

"(1) Enter into cooperative agreements or contracts with public or private entities to review the available scientific evidence concerning such drugs.

"(2) Seek public input concerning such drugs, including input on whether there is a relevant accepted use in clinical practice that is not reflected in the approved labeling of such drugs or whether new scientific evidence is available regarding the conditions of use for such drug, by—

"(A) holding one or more public meetings;

"(B) opening a public docket for the submission of public comments; or

"(C) other means, as the Secretary determines appropriate.

"(c) SELECTION OF DRUGS FOR UPDATING.—If the Secretary determines, with respect to a covered drug, that the available scientific evidence meets the standards under section 505 for adding or modifying information to the labeling or providing supplemental information to the labeling regarding the use of the covered drug, the Secretary may initiate the process under subsection (d).

"(d) INITIATION OF THE PROCESS OF UPDATING.—If the Secretary determines that labeling changes are appropriate for a selected drug pursuant to subsection (c), the Secretary shall provide notice to the holders of approved applications for a generic version of such drug that—

"(1) summarizes the findings supporting the determination of the Secretary that the available scientific evidence meets the standards under section 505 for adding or modifying information or providing supplemental information to the labeling of the covered drug pursuant to subsection (c);

"(2) provides a clear statement regarding the additional, modified, or supplemental information for such labeling, according to the determination by the Secretary (including, as applicable, modifications to add the relevant accepted use to the labeling of the drug as an additional indication for the drug); and

"(3) states whether the statement under paragraph (2) applies to the selected drug as a class of covered drugs or only to a specific drug product.

"(e) RESPONSE TO NOTIFICATION.—Within 30 days of receipt of notification provided by the Secretary pursuant to subsection (d), the holder of an approved application for a generic version of the selected drug shall—

"(1) agree to change the approved labeling to reflect the additional, modified, or supplemental information the Secretary has determined to be appropriate; or

"(2) notify the Secretary that the holder of the approved application does not believe that the requested labeling changes are warranted and submit a statement detailing the reasons why such changes are not warranted.

"(f) REVIEW OF APPLICATION HOLDER'S RESPONSE.—

"(1) IN GENERAL.—Upon receipt of the application holder's response, the Secretary shall promptly review each statement received under subsection (e)(2) and determine which labeling changes pursuant to the Secretary's notice under subsection (d) are appropriate, if any. If the Secretary disagrees with the reasons why such labeling changes are not warranted, the Secretary shall provide opportunity for discussions with the application holders to reach agreement on whether the labeling for the covered drug should be updated to reflect available scientific evidence, and if so, the content of such labeling changes.

"(2) CHANGES TO LABELING.—After considering all responses from the holder of an approved application under paragraph (1) or (2) of subsection (e), and any discussion under paragraph (1), the Secretary may order such holder to make the labeling changes the Secretary determines are appropriate. Such holder of an approved application shall—

"(A) update its paper labeling for the drug at the next printing of that labeling;

"(B) update any electronic labeling for the drug within 30 days of such order; and

"(C) submit the revised labeling through the form, 'Supplement—Changes Being Effected'.

"(g) VIOLATION.—If the holder of an approved application for the generic version of the selected drug does not comply with the requirements of subsection (f)(2), such generic version of the selected drug shall be deemed to be misbranded under section 502.

"(h) LIMITATIONS; GENERIC DRUGS.—

"(1) IN GENERAL.—With respect to any labeling change required under this section, the generic version shall be deemed to have the same conditions of use and the same labeling as its reference listed drug for purposes of clauses (i) and (v) of section 505(j)(2)(A). Any labeling change so required shall not have any legal effect for the applicant that is different than the legal effect that would have resulted if a supplemental application had been submitted and approved to conform the labeling of the generic version to a change in the labeling of the reference drug.

"(2) SUPPLEMENTAL APPLICATIONS.—Changes to labeling made in accordance with this section shall not be eligible for an exclusivity period under this Act.

"(3) SELECTION OF DRUGS.—Nothing in this section shall be construed to give the Secretary the authority to identify a drug as a covered drug or select a drug label for updating solely based on the availability of new safety information. Upon identification of a drug as a covered drug, the Secretary may then consider the availability of new, additional, or different safety information in determining whether the drug is a selected drug and in determining what labeling changes are appropriate.

"(4) MAINTENANCE OF LABELING.—Nothing in this section shall be construed to affect the responsibility of the holder of an approved application under section 505(j) to maintain its labeling in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 314.97 of title 21, Code of Federal Regulations (or any successor regulations).

"(i) RULES OF CONSTRUCTION.—

"(1) APPROVAL STANDARDS.—This section shall not be construed as altering the applicability of the standards for approval of an application under section 505. No order shall be issued under this subsection unless the scientific evidence supporting the changed labeling meets the standards for approval applicable to any change to labeling under section 505.

"(2) SECRETARY AUTHORITY.—Nothing in this section shall be construed to limit the authority of the Secretary to require labeling changes under section 505(o).

"(j) REPORTS.—Not later than 4 years after the date of the enactment of the Making Objective Drug Evidence Revisions for New Labeling Act of 2020, and every 4 years thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, a report that—

"(1) describes the actions of the Secretary under this section, including—

"(A) the number of covered drugs and description of the types of drugs the Secretary has selected for labeling changes and the rationale for such recommended changes; and

"(B) the number of times the Secretary entered into discussions concerning a disagreement with an application holder or holders and a summary of the decision regarding a labeling change, if any; and

"(2) includes any recommendations of the Secretary for modifying the program under this section.".

I. PURPOSE AND SUMMARY

H.R. 5668, the "Making Objective Drug Evidence Revisions for New Labeling Act of 2020", or the "MODERN Labeling Act of 2020", introduced by Reps. Doris O. Matsui (D–CA) and Brent Guthrie (R–KY), provides additional authority to the Food and Drug Administration (FDA) to require modifications of outdated labeling for certain generic drugs to ensure such labeling includes complete and accurate information. The bill would also require FDA to report to Congress any actions taken under this new authority to update labeling for such generic drugs, including the number of drugs, description of the changes and the rationale, as well as any FDA recommendation(s) to modify the program, among other things.

II. BACKGROUND AND NEED FOR LEGISLATION

Prescription drug product labeling contains information regarding the product based on an FDA analysis of the sponsor's new drug application or biologics license application. Labeling approved by FDA must contain all relevant information needed to support the safe and effective use of that drug product, such as conditions of use (including dosage and administration), warnings, contraindications, and any adverse reactions. Drug sponsors are required to update a marketed product's label as new information about the drug, such as new indications or safety-related information, becomes available. Generic drugs are generally required to have the same labeling as the brand drug they reference and generic drug manufacturers are not permitted to independently update labeling of their product to include new safety-related information if that information does not follow the approved labeling of the brand drug product.

Labeling for brand drug products, however, does not always reflect new information about those products, such as new uses or safety information discovered after post-market use.[1] This may be due to the lack of sufficient incentives for manufacturers to submit supplements to continually update their product labeling to include new scientific information, such as new uses, or because a brand drug has left the market and the brand drug manufacturer can no longer update the labeling when necessary.[2] A recent study found that most oncology drug labels do not contain all appropriate uses, leaving providers and patients without labeling information reflecting all relevant efficacy information.[3]

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[1] Shea, M; Stewart, M; Van Dyke, H; Ostermann, L; Allen, J; Sigal, E. 2018. *Outdated Prescription Drug Labeling: How FDA-Approved Prescribing Information Lags Behind Real-World Clinical Practice. Therapeutic Innovation and Regulatory Science.* DIA. (doi.org/10.1177/2168479018759662).

[2] *Id.*

[3] *Id.*

H.R. 5668 would help ensure that generic drug labels provide health care providers and patients with accurate and complete information about the use of the drug when the brand drug is no longer marketed. Specifically, this legislation would create a pathway to update labels in these circumstances and would provide FDA with the authority to require updated labeling to reflect current legal and regulatory requirements, such as the content and format requirements outlined in the 2006 Physician Labeling Rule. According to the FDA, "Modernizing labeling to reflect the content and format requirements outlined in that rule could substantially increase the usefulness of the labeling as a communication tool to healthcare providers and other stakeholders."[4] Further, the agency has noted that the legislation would enable FDA to ensure generic labeling provides current information about existing and new conditions of use, in a modern format, "all of which could help facilitate broader use of lower cost generic medicines."[5]

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. 5668:

The Subcommittee on Health held a legislative hearing on January 29, 2020, on H.R. 5668 and nine other bills. The hearing was entitled "Improving Safety and Transparency in America's Food and Drugs." 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.

[4] FDA Technical Assistance on the "Making Objective Drug Evidence Revisions for New Labeling Act of 2020," or the MODERN Labeling Act, prepared on February 27, 2020.
[5] *Id.*

- 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

Reps. Matsui and Guthrie introduced H.R. 5668 on January 24, 2020, and the bill was referred to the Committee on Energy and Commerce. H.R. 5668 was then referred to the Subcommittee on Health on January 25, 2020. A legislative hearing on the bill was held on January 29, 2020.

The Subcommittee met in open markup session on March 11, 2020, pursuant to notice, to consider H.R. 5668 and twelve other bills. During consideration of the bill, an amendment offered by Ms. Matsui was agreed to by a voice vote. Upon conclusion of consideration of the bill, the Subcommittee agreed to forward H.R. 5668 favorably to the full Committee, amended, by a voice vote, a quorum being present.

On July 15, 2020, the full Committee met in virtual open markup session, pursuant to notice, to consider H.R. 5668 and twenty-nine other bills. During consideration of the bill, an amendment in the nature of a substitute offered by Ms. Matsui, on behalf of herself and Mr. Guthrie, was agreed to by a voice vote. Upon conclusion of consideration of the bill, the full Committee agreed to a motion of final passage offered by Mr. Pallone, Chairman of the committee, to order H.R. 5668 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. 5668, including the motion on 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.

VIII. CONGRESSIONAL BUDGET OFFICE ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, October 29, 2020.

Hon. FRANK PALLONE, JR.,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 5668, the Making Objective Drug Evidence Revisions for New Labeling Act of 2020.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Ellen Werble.

Sincerely,

PHILLIP L. SWAGEL,
Director.

Enclosure.

H.R. 5668, Making Objective Drug Evidence Revisions for New Labeling Act of 2020

As ordered reported by the House Committee on Energy and Commerce on July 15, 2020

By Fiscal Year, Millions of Dollars	2021	2021-2025	2021-2030
Direct Spending (Outlays)	0	0	0
Revenues	0	0	0
Increase or Decrease (-) in the Deficit	0	0	0
Spending Subject to Appropriation (Outlays)	*	*	not estimated

Statutory pay-as-you-go procedures apply?	No	**Mandate Effects**	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2031?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	Yes, Under Threshold

* = between zero and $500,000.

Under current law, labels on generic drugs must match those of their corresponding reference brand drug. H.R. 5668 would allow the Secretary of Health and Human Services to require label updates for certain generic drugs once the reference drug's patents and exclusivities expire, new information is available, and the Secretary determines that the public health would benefit from the updated label. The bill also would require the Secretary to report to the Congress every four years on the number and types of such determinations made and on the number of times manufacturers disagreed with those determinations.

CBO expects that over the 2021–2025 period, implementing H.R. 5668 would require the work of less than one full-time staff member of the Food and Drug Administration. CBO estimates the cost would fall below $500,000 over the 2021–2025 period, although the amount could be higher if the Secretary determines that a significant number of labels require updates. Any spending would be subject to the availability of appropriated funds.

H.R. 5668 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA) by requiring manufacturers of certain drugs to update product labels. Because this requirement is not expected to apply to a large number of products in the first few years, CBO estimates that the aggregate cost would fall below the private-sector threshold established in UMRA ($168 million in 2020, adjusted annually for inflation).

On July 16, 2019, CBO transmitted a cost estimate for S. 1895, the Lower Health Care Costs Act, as ordered reported by the Senate Committee on Health, Education, Labor, and Pensions on June 26, 2019. Section 213 of S. 1895 is similar to H.R. 5668, and CBO's estimates of their costs are the same.

The CBO staff contacts for this estimate are Ellen Werble (for federal costs) and Andrew Laughlin (for mandates). The estimate was reviewed by Leo Lex, Deputy Director of Budget Analysis.

IX. 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.

X. 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 provide the FDA with new authorities to modernize labeling requirements for certain generic drug products to allow the agency to require changes to the labeling to reflect new information or scientific evidence about a generic drug when the brand drug product is no longer marketed.

XI. Duplication of Federal Programs

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 5668 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.

XII. 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.

XIII. 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. 5668 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIV. Advisory Committee Statement

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

XV. 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.

XVI. Section-by-Section Analysis of the Legislation

Section 1. Short title

Section 1 designates that the short title may be cited as the "Making Objective Evidence Revisions for New Labeling Act of 2020" or the "MODERN Labeling Act of 2020".

Sec. 2. Modernizing the labeling of certain generic drugs

Section 2 amends the Federal Food, Drug, and Cosmetic Act (FFDCA) by inserting a new section that authorizes a process to update labeling for certain generic drugs, known as a "covered drug". The legislation defines the term "covered drug" as a drug approved under section 505(c) for which (1) there are no unexpired patents included in the list under section 505(j)(7) and no unexpired period of exclusivity, (2) the approval of the application has been withdrawn for reasons other than safety or effectiveness, and (3) there is new scientific evidence available pertaining to the existing conditions of use that is not reflected in the labeling, the approved labeling does not reflect current legal and regulatory requirements for content or format, or there is a relevant accepted use in clinical practice that is not reflected in the approved labeling, and updating the labeling would benefit public health. This section also defines "generic version" as a drug approved under section 505(j) whose reference listed drug is a covered drug; "relevant accepted use" as a use for a drug in clinical practice that is supported by scientific evidence that appears to the Secretary of Health and Human Services (the Secretary) to meet the standards for approval under section 505; and "selected drug" as a covered drug for which the Secretary has determined through the process under subsection (c) that the labeling should be changed.

Subsection (b) states that the Secretary may identify covered drugs for which labeling updates would provide a public health benefit. To assist with this, the Secretary may do one or both of the following: enter into cooperative agreements or contracts with public or private entities to review available scientific evidence concerning such drugs, or seek public input on whether there is relevant accepted use in clinical practice that is not reflected in the approved labeling of such drugs or whether new scientific evidence is available regarding the conditions of use for such drug, by (1) holding one or more public meetings, (2) opening a public docket for the submission of public comments, or (3) other means as the Secretary deems appropriate.

Subsection (c) states that if the Secretary determines, with respect to a covered drug, that the available scientific evidence meets the standards under section 505 of the FFDCA for adding or modifying information to the labeling or providing supplemental information to the labeling regarding the use of the covered drug, the Secretary may initiate this process under subsection (d).

Subsection (d) states that if the Secretary determines that labeling changes are appropriate for a selected drug, the Secretary shall provide notice to the holders of the approved applications for a generic version of the drug that (1) summarizes the findings supporting the determination of the Secretary, (2) provides a clear statement regarding the additional, modified, or supplemental information for such labeling, according to the determination by the Secretary, and (3) states whether that statement applies to the selected drug as a class of covered drugs or only to a specific drug product.

Subsection (e) states that within 30 days of receipt of the aforementioned notice provided by the Secretary, the holder of the approved application for a generic version of the selected drug shall (1) agree to change the approved labeling to reflect the additional, modified, or supplemental information the Secretary has determined to be appropriate, or (2) notify the Secretary that the holder of the approved application does not believe that the requested label changes are warranted and submit a statement detailing the reasons why such changes are not warranted.

Subsection (f), upon receipt of the holder's response, requires the Secretary to promptly review each statement and determine which labeling changes pursuant to the Secretary's notice are appropriate, if any. If the Secretary disagrees with the reasons why such labeling changes are not warranted, the Secretary shall provide opportunity for discussions with the application holders to reach agreement on whether the labeling for the covered drug should be updated to reflect availability scientific evidence and if so, the content of such labeling changes. After considering all responses from the holder, and any further discussion, the Secretary may order such holder to make the labeling changes the Secretary determines are appropriate. Such holder of an approved application shall then (1) update its paper labeling for the drug at the next printing of that labeling, (2) update any electronic labeling for the drug within 30 days of such order, and (3) submit the revised labeling through the form "Supplement—Changes Being Effected."

Subsection (g) states that if a holder of an approved application for the generic version of the selected drug does not comply with the requirements of the Secretary's order, such generic version of the selected drug shall be deemed to be misbranded under section 502 of the FFDCA.

Subsection (h) states that the generic version shall be deemed to have the same conditions of use and the same labeling as its reference listed drug with respect to any labeling change required under this section. Any labeling change shall not have any legal effect for the applicant that is different than the legal effect that would have resulted from an approved supplemental application to conform the labeling of the generic version to the change in labeling for the reference listed drug. In addition, the subsection states that changes to labeling made in accordance with this section shall not be eligible for an exclusivity period under this Act. Further, the subsection clarifies that nothing in this section shall be construed to give the Secretary the authority to identify a drug as a covered drug or select a drug label for updating solely based on the availability of new safety information. Upon identification of a drug as a covered drug, the Secretary may then consider the availability of

new, additional, or different safety information in determining what labeling changes are appropriate. Finally, the subsection makes clear that nothing in this section shall be construed to affect the responsibility of the holder of an approved application to maintain its labeling in accordance with existing regulatory requirements.

Subsection (i) states that this section shall not be construed as altering the applicability of the standards for approval of an application under section 505 of FFDCA and that no order shall be issued under this subsection unless the scientific evidence supporting the changed labeling meets the standards for approval applicable to any change to labeling under section 505. Further, the subsection states that nothing in this section shall be construed to limit the authority of the Secretary to require changes under section 505(o) of the FFDCA.

Subsection (j) states that not later than four years after the date of enactment of the "MODERN Labeling Act of 2020", and every four years thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, a report that (1) describes the actions of the Secretary under this section, including the number of covered drugs and description of the types of drugs the Secretary has selected for labeling changes and the rationales for such recommended changes, and the number of times the Secretary entered into discussions concerning a disagreement with an application holder or holders and a summary of the decision regarding a labeling change, if any; and (2) includes any recommendations of the Secretary for modifying the program under this section.

XVII. 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 (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

SUBCHAPTER A—DRUGS AND DEVICES

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SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN DRUGS.

(a) DEFINITIONS.—For purposes of this section:

(1) The term "covered drug" means a drug approved under section 505(c)—

(A) for which there are no unexpired patents included in the list under section 505(j)(7) and no unexpired period of exclusivity;

(B) for which the approval of the application has been withdrawn for reasons other than safety or effectiveness; and

(C) for which—

(i)(I) there is new scientific evidence available pertaining to the existing conditions of use that is not reflected in the labeling;

(II) the approved labeling does not reflect current legal and regulatory requirements for content or format; or

(III) there is a relevant accepted use in clinical practice that is not reflected in the approved labeling; and

(ii) updating the labeling would benefit the public health.

(2) The term "period of exclusivity", with respect to a drug approved under section 505(c), means any period of exclusivity under clause (ii), (iii), or (iv) of section 505(c)(3)(E), clause (ii), (iii), or (iv) of section 505(j)(5)(F), or section 505A, 505E, or 527.

(3) The term "generic version" means a drug approved under section 505(j) whose reference listed drug is a covered drug.

(4) The term "relevant accepted use" means a use for a drug in clinical practice that is supported by scientific evidence that appears to the Secretary to meet the standards for approval under section 505.

(5) The term "selected drug" means a covered drug for which the Secretary has determined through the process under subsection (c) that the labeling should be changed.

(b) IDENTIFICATION OF COVERED DRUGS.—The Secretary may identify covered drugs for which labeling updates would provide a public health benefit. To assist in identifying covered drugs, the Secretary may do one or both of the following:

(1) Enter into cooperative agreements or contracts with public or private entities to review the available scientific evidence concerning such drugs.

(2) Seek public input concerning such drugs, including input on whether there is a relevant accepted use in clinical practice that is not reflected in the approved labeling of such drugs or whether new scientific evidence is available regarding the conditions of use for such drug, by—

(A) holding one or more public meetings;

(B) opening a public docket for the submission of public comments; or

(C) other means, as the Secretary determines appropriate.

(c) SELECTION OF DRUGS FOR UPDATING.—If the Secretary determines, with respect to a covered drug, that the available scientific evidence meets the standards under section 505 for adding or modifying information to the labeling or providing supplemental information to the labeling regarding the use of the covered drug, the Secretary may initiate the process under subsection (d).

(d) INITIATION OF THE PROCESS OF UPDATING.—If the Secretary determines that labeling changes are appropriate for a selected drug pursuant to subsection (c), the Secretary shall provide notice to the holders of approved applications for a generic version of such drug that—

(1) summarizes the findings supporting the determination of the Secretary that the available scientific evidence meets the standards under section 505 for adding or modifying information or providing supplemental information to the labeling of the covered drug pursuant to subsection (c);

(2) provides a clear statement regarding the additional, modified, or supplemental information for such labeling, according to the determination by the Secretary (including, as applicable, modifications to add the relevant accepted use to the labeling of the drug as an additional indication for the drug); and

(3) states whether the statement under paragraph (2) applies to the selected drug as a class of covered drugs or only to a specific drug product.

(e) RESPONSE TO NOTIFICATION.—Within 30 days of receipt of notification provided by the Secretary pursuant to subsection (d), the holder of an approved application for a generic version of the selected drug shall—

(1) agree to change the approved labeling to reflect the additional, modified, or supplemental information the Secretary has determined to be appropriate; or

(2) notify the Secretary that the holder of the approved application does not believe that the requested labeling changes are warranted and submit a statement detailing the reasons why such changes are not warranted.

(f) REVIEW OF APPLICATION HOLDER'S RESPONSE.—

(1) IN GENERAL.—Upon receipt of the application holder's response, the Secretary shall promptly review each statement received under subsection (e)(2) and determine which labeling changes pursuant to the Secretary's notice under subsection (d) are appropriate, if any. If the Secretary disagrees with the reasons why such labeling changes are not warranted, the Secretary shall provide opportunity for discussions with the application holders to reach agreement on whether the labeling for the covered drug should be updated to reflect available scientific evidence, and if so, the content of such labeling changes.

(2) CHANGES TO LABELING.—After considering all responses from the holder of an approved application under paragraph (1) or (2) of subsection (e), and any discussion under paragraph (1), the Secretary may order such holder to make the labeling changes the Secretary determines are appropriate. Such holder of an approved application shall—

(A) update its paper labeling for the drug at the next printing of that labeling;

(B) update any electronic labeling for the drug within 30 days of such order; and

(C) submit the revised labeling through the form, "Supplement—Changes Being Effected".

(g) VIOLATION.—If the holder of an approved application for the generic version of the selected drug does not comply with the requirements of subsection (f)(2), such generic version of the selected drug shall be deemed to be misbranded under section 502.

(h) LIMITATIONS; GENERIC DRUGS.—

(1) IN GENERAL.—With respect to any labeling change required under this section, the generic version shall be deemed to have the same conditions of use and the same labeling as its

reference listed drug for purposes of clauses (i) and (v) of section 505(j)(2)(A). Any labeling change so required shall not have any legal effect for the applicant that is different than the legal effect that would have resulted if a supplemental application had been submitted and approved to conform the labeling of the generic version to a change in the labeling of the reference drug.

(2) SUPPLEMENTAL APPLICATIONS.—Changes to labeling made in accordance with this section shall not be eligible for an exclusivity period under this Act.

(3) SELECTION OF DRUGS.—Nothing in this section shall be construed to give the Secretary the authority to identify a drug as a covered drug or select a drug label for updating solely based on the availability of new safety information. Upon identification of a drug as a covered drug, the Secretary may then consider the availability of new, additional, or different safety information in determining whether the drug is a selected drug and in determining what labeling changes are appropriate.

(4) MAINTENANCE OF LABELING.—Nothing in this section shall be construed to affect the responsibility of the holder of an approved application under section 505(j) to maintain its labeling in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 314.97 of title 21, Code of Federal Regulations (or any successor regulations).

(i) RULES OF CONSTRUCTION.—

(1) APPROVAL STANDARDS.—This section shall not be construed as altering the applicability of the standards for approval of an application under section 505. No order shall be issued under this subsection unless the scientific evidence supporting the changed labeling meets the standards for approval applicable to any change to labeling under section 505.

(2) SECRETARY AUTHORITY.—Nothing in this section shall be construed to limit the authority of the Secretary to require labeling changes under section 505(o).

(j) REPORTS.—Not later than 4 years after the date of the enactment of the Making Objective Drug Evidence Revisions for New Labeling Act of 2020, and every 4 years thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, a report that—

(1) describes the actions of the Secretary under this section, including—

(A) the number of covered drugs and description of the types of drugs the Secretary has selected for labeling changes and the rationale for such recommended changes; and

(B) the number of times the Secretary entered into discussions concerning a disagreement with an application holder or holders and a summary of the decision regarding a labeling change, if any; and

(2) includes any recommendations of the Secretary for modifying the program under this section.

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