AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 5668

OFFERED BY M__. _____

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''(B) for which the approval of the application has been withdrawn for reasons other than safety or effectiveness; and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

lect 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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