AMENDMENT TO H.R. 4221

OFFERED BY M__. _____

[[Page/line numbers refer to the draft dated June 30, 2023 (11:58 a.m.)]

At the end of title I, add the following:

SEC. 113. EXTENDED EXPIRATION DATES FOR LIFE-SAVING DRUGS.

(a) DATA AND INFORMATION.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') may issue an order requiring the manufacturer of a life-saving drug to submit, in such manner as the Secretary may prescribe, data and information from any stage of development of the drug that are adequate to assess the stability of the drug to determine the longest supported expiration date.

(2) LACK OF DATA AND INFORMATION.—If the data and information required pursuant to an order issued under paragraph (1) are not available or are insufficient, as determined by the Secretary, the Secretary may issue an order requiring the manufacturer of the drug—

(A) to conduct studies, which may be a continuation of ongoing studies, to provide data and information adequate to assess the stability of the drug and to determine the longest supported expiration date; and

(B) to submit such data and information to the Secretary in such manner as the Secretary may prescribe in the order.

(b) LABELING.—The Secretary may issue an order requiring the manufacturer of a life-saving drug, by a date determined by the Secretary in consultation with the sponsor of the drug, to make any labeling change regarding the expiration date or storage and handling of the drug that the Secretary determines to be appropriate based on the data and information required to be submitted under this section or any other data and information available to the Secretary.

(c) CONFIDENTIALITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(d) PENALTIES.—If a manufacturer of a life-saving drug fails to submit data and information as required under subsection (a)(1), fails to conduct or submit the

data and information generated by studies as required under subsection (a)(2), or fails to make a labeling change as required under subsection (b), such manufacturer shall be subject to a civil penalty of not more than $10,000 for the first day on which the violation occurs and not more than $10,000 for each subsequent day on which the violation is not corrected.

(e) DEFINITIONS.—In this section:

(1) DRUG.—The term ''drug'' has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301).

(2) LIFE-SAVING DRUG.—The term ''life-saving drug'' means a drug, that is—

(A)(i) a medical countermeasure; or

(ii) on the drug shortage list under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e) or determined by the Secretary to be at risk of shortage; and

(B)(i) life-supporting;

(ii) life-sustaining; or

(iii) intended for use in the prevention or treatment of a debilitating disease or condition in humans or animals, including any such drug used in emergency medical care or during surgery or any such drug that is critical to the

public health during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d).

(3) MEDICAL COUNTERMEASURE.—The term ''medical countermeasure'' means a countermeasure as defined in section 565(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4).