H. R. 2617

One Hundred Seventeenth Congress of the United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Monday, the third day of January, two thousand and twenty-two

An Act

Making consolidated appropriations for the fiscal year ending September 30, 2023, and for providing emergency assistance for the situation in Ukraine, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Consolidated Appropriations Act, 2023".

SEC. 2. TABLE OF CONTENTS.

"(5) The requirements of paragraphs (1) and (2) shall apply regardless of whether the drug or device undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States.".

(b) UPDATING REGULATIONS.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall update regulations, as appropriate, to implement the amendment made by subsection (a).

SEC. 2512. EXTENDING EXPIRATION DATES FOR CERTAIN DRUGS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall issue draft guidance, or revise existing guidance, to address recommendations for sponsors of applications submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) regarding—

(1) the submission of stability testing data in such applications, including considerations for data requirements that could be streamlined or reduced to facilitate faster review of longer proposed expiration dates;

(2) establishing in the labeling of drugs the longest feasible expiration date scientifically supported by such data, taking into consideration how extended expiration dates may—

(A) help prevent or mitigate drug shortages; and

(B) affect product quality; and

(3) the use of innovative approaches for drug and combination product stability modeling to support initial product expiration dates and expiration date extensions.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, and again 2 years thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

(1) the number of drugs for which the Secretary has requested the manufacturer make a labeling change regarding the expiration date; and

(2) for each drug for which the Secretary has requested a labeling change with respect to the expiration date, information regarding the circumstances of such request, including—

(A) the name and dose of such drug;

(B) the rationale for the request;

(C) whether the drug, at the time of the request, was listed on the drug shortage list under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), or was at risk of shortage;

(D) whether the request was made in connection with a public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d); and

(E) whether the manufacturer made the requested change by the requested date, and for instances where the manufacturer does not make the requested change, the manufacturer's justification for not making the change, if the manufacturer agrees to provide such justification for inclusion in the report.