H. R.____

To amend the Federal Food, Drug, and Cosmetic Act to authorize the Secretary of Health and Human Services to consider the potential for misuse and abuse when determining whether to approve certain drugs, and for other purposes

IN THE HOUSE OF REPRESENTATIVES

Mr. Gene Green of Texas introduced the following bill; which was referred to the Committee on

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize the Secretary of Health and Human Services to consider the potential for misuse and abuse when determining whether to approve certain drugs, 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 “Saving American Families through Efficacy and Trusted Ways Act of 2018” or the “SAFETY Act of 2018”.
SEC. 2. CONSIDERATION OF POTENTIAL FOR MISUSE AND

ABUSE REQUIRED FOR DRUG APPROVAL.

(a) IN GENERAL.—Section 505(d) of the Federal
Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is
amended—

(1) in the first sentence—

(A) by striking “or (7)” and inserting
“(7)”; and

(B) by inserting “; or (8) if the drug is or
contains a controlled substance for which a list-
ing in any schedule is in effect under the Con-
trolled Substances Act or that is permanently
scheduled pursuant to section 201 of such Act,
on the basis of information submitted to him as
part of the application, or upon the basis of any
other information before him with respect to
such drug, the drug is unsafe for use due to the
risks of abuse or misuse or there is insufficient
information to show that the drug is safe for
use considering such risks;” before “he shall
issue an order refusing to approve the applica-
tion”; and

(2) in the second sentence, by striking “(6)”
and inserting “(8)”.

(b) **Withdrawal Authority.**—Section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) is amended in the first sentence—

(1) by striking “or (5)” and inserting “(5)”;

and

(2) by inserting the following: “; or (6) that, in the case of a drug that is or contains a controlled substance for which a listing in any schedule is in effect under the Controlled Substances Act or that is permanently scheduled pursuant to section 201 of such Act, on the basis of new information before him with respect to such drug, evaluated together with the information available to him when the application was approved, that the drug is unsafe for use due to the risks of abuse or misuse” after “of a material fact”.

(c) **Rule of Construction.**—Nothing in the amendments made by this section shall be construed to limit or narrow, in any manner, the meaning or application of the provisions of paragraphs (1), (2), (3), (4), (5), and (7) of section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) or paragraphs (1) and (2) of section 505(e) of such Act (21 U.S.C. 355(e)).