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(Original Signature of Member)

115TH CONGRESS
2D SESSION

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

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IN THE HOUSE OF REPRESENTATIVES

M__. _____ 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. 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 before the period at the end the following: ''; or (8) if the drug is or contains a controlled substance for which a listing in any schedule is in effect (on a temporary or permanent basis) under section 201 of the Controlled Substances Act, upon 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''; and

(2) in the second sentence, by striking ''(6)'' and inserting ''(6) and (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 (on a temporary or permanent basis) under section 201 of the Controlled Substances 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 ''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) through (5) 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)).