AMENDMENT TO H.R. ____

OFFERED BY MR. GENE GREEN OF TEXAS

Add at the end of the bill the following new section (and make such conforming changes as may be necessary):

SEC. ___. 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 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 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 application''; 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)).