AMENDMENT NO._______ Calendar No.______

Purpose: To modify and limit certain exemptions to the Freedom of Information Act.


S. 3187

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

Referred to the Committee on ________ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by

__________

Viz:

1. On page 192, strike line 10 through line 21 and insert the following:

2. (2) by adding at the end the following:

“(b) ABILITY TO RECEIVE AND PROTECT CONFIDENTIAL INFORMATION OBTAINED FROM FOREIGN GOVERNMENTS.—

“(1) IN GENERAL.—The Secretary shall not be required to disclose under section 552 of title 5, United States Code (commonly referred to as the Freedom of Information Act), or any other provision
of law, any information described in subsection (e)(3) obtained from a foreign government agency, if—

“(A) the information is provided or made available to the United States Government voluntarily and on the condition that the information not be released to the public; and

“(B) the information is covered by, and subject to, a certification and written agreement under subsections (c)(1) and (c)(2).

“(2) TIME LIMITATIONS.—The written agreement described in subsection (c)(2) shall specify the time period for which the non-disclosure requirements under paragraph (1) shall apply to the voluntarily disclosed information. The non-disclosure requirements under paragraph (1) shall not apply after the date specified, but all other applicable legal protections, including section 552 of title 5, United States Code and section 319L(c)(1) of the Public Health Service Act, shall continue to apply to such information, as appropriate. If no date is specified in the written agreement, the non-disclosure protections described in paragraph (1) shall not exceed 3 years.
“(3) DISCLOSURES NOT AFFECTED.—Nothing in this section authorizes any official to withhold, or to authorize the withholding of, information from Congress or information required to be disclosed pursuant to an order of a court of the United States.

“(4) PUBLIC INFORMATION.—For purposes of section 552 of title 5, United States Code, this subsection shall be considered a statute described in section 552(b)(3)(B).”.