

AMENDMENT NO. _____ Calendar No. _____

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

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

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 in-
2 sert the following:

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

4 “(b) ABILITY TO RECEIVE AND PROTECT CONFIDEN-
5 TIAL INFORMATION OBTAINED FROM FOREIGN GOVERN-
6 MENTS.—

7 “(1) IN GENERAL.—The Secretary shall not be
8 required to disclose under section 552 of title 5,
9 United States Code (commonly referred to as the
10 Freedom of Information Act), or any other provision

1 of law, any information described in subsection
2 (c)(3) obtained from a foreign government agency,
3 if—

4 “(A) the information is provided or made
5 available to the United States Government vol-
6 untarily and on the condition that the informa-
7 tion not be released to the public; and

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

11 “(2) TIME LIMITATIONS.—The written agree-
12 ment described in subsection (c)(2) shall specify the
13 time period for which the non-disclosure require-
14 ments under paragraph (1) shall apply to the volun-
15 tarily disclosed information. The non-disclosure re-
16 quirements under paragraph (1) shall not apply
17 after the date specified, but all other applicable legal
18 protections, including section 552 of title 5, United
19 States Code and section 319L(e)(1) of the Public
20 Health Service Act, shall continue to apply to such
21 information, as appropriate. If no date is specified
22 in the written agreement, the non-disclosure protec-
23 tions described in paragraph (1) shall not exceed 3
24 years.

1 “(3) DISCLOSURES NOT AFFECTED.—Nothing
2 in this section authorizes any official to withhold, or
3 to authorize the withholding of, information from
4 Congress or information required to be disclosed
5 pursuant to an order of a court of the United
6 States.

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