

.....
(Original Signature of Member)

116TH CONGRESS
2D SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to require the Secretary to refer each application for review of certain tobacco products to the Tobacco Products Scientific Advisory Committee, and for other purposes.

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 require the Secretary to refer each application for review of certain tobacco products to the Tobacco Products Scientific Advisory Committee, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Independent Advisory
5 Committee Review of E-Cigarette Applications Act”.

1 **SEC. 2. REQUIRED REFERRAL TO TOBACCO PRODUCTS SCI-**
2 **ENTIFIC ADVISORY COMMITTEE.**

3 (a) IN GENERAL.—Section 910(b)(2) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 387j(b)(2)) is
5 amended to read as follows:

6 “(2) REFERRAL TO TOBACCO PRODUCTS SCI-
7 ENTIFIC ADVISORY COMMITTEE.—Upon receipt of an
8 application meeting the requirements set forth in
9 paragraph (1), the Secretary shall—

10 “(A) provide a written notification of such
11 application to the Tobacco Products Scientific
12 Advisory Committee; and

13 “(B) in the case of an application with re-
14 spect to which the Secretary intends to issue an
15 order under subsection (c)(1)(A)(i), to enable
16 the Advisory Committee to carry out paragraph
17 (3), refer such application to the Advisory Com-
18 mittee for review prior to issuance of such an
19 order.”.

20 (b) TOBACCO PRODUCTS SCIENTIFIC ADVISORY COM-
21 MITTEE.—Section 910(b) of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 387j(b)) is amended by adding
23 at the end the following:

24 “(3) TOBACCO PRODUCTS SCIENTIFIC ADVISORY
25 COMMITTEE.—The Tobacco Products Scientific Ad-
26 visory Committee shall—

1 “(A) within such period as the Secretary
2 may establish, submit to the Secretary a report
3 and recommendation with respect to an applica-
4 tion referred to the Advisory Committee under
5 paragraph (2), together with all underlying data
6 and the reasons or basis for the recommenda-
7 tion (including the results of each vote taken
8 under subparagraph (B));

9 “(B) before issuing a report or rec-
10 ommendation with respect to an application
11 under subparagraph (A), take a public vote on
12 whether to recommend that the Secretary issue
13 an order under subsection (c)(1)(A)(i) with re-
14 spect to the application; and

15 “(C) make publicly available a list of all
16 applications with respect to which the Advisory
17 Committee has received a notification under
18 paragraph (2)(A) that, with respect to each
19 such application, identifies the applicant and
20 each product that is the subject of the applica-
21 tion.

22 “(4) ASSISTANCE.—The Secretary shall take all
23 actions necessary to assist the Advisory Committee
24 in carrying out its duties under this section.”.