

119TH CONGRESS
2D SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to add alpha-gal
to the definition of “major food allergen”.

IN THE SENATE OF THE UNITED STATES

Mr. WARNER introduced the following bill; which was read twice and referred
to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to
add alpha-gal to the definition of “major food allergen”.

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 “Alpha-gal Allergen In-
5 clusion Act”.

6 **SEC. 2. ADDING ALPHA-GAL TO DEFINITION OF “MAJOR**
7 **FOOD ALLERGEN”.**

8 (a) IN GENERAL.—Section 201(qq) of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 321(qq)) is
10 amended by adding at the end the following:

1 “(3)(A) Galactose-alpha-1,3-galactose (com-
2 monly known as ‘alpha-gal’).

3 “(B) For purposes of this subparagraph, the
4 term ‘galactose-alpha-1,3-galactose’ includes—

5 “(i) ingredients derived from non-
6 catarrhine primate mammals; and

7 “(ii) red algae in the order Gigartinales.

8 “(C) For purposes of this subparagraph, the
9 term ‘galactose-alpha-1,3-galactose’ does not include
10 mammal-derived ingredients for which the Secretary
11 determines there is no galactose-alpha-1,3-galactose
12 above an established, detectable limit (such as ingre-
13 dients made from alpha-gal-knockout mammals).”.

14 (b) EFFECTIVE DATE.—The amendment made by
15 subsection (a) shall apply beginning on the date that is
16 18 months after the date of enactment of this Act.