117TH CONGRESS
2D SESSION

S. 5316

To protect access to kratom.

IN THE SENATE OF THE UNITED STATES

DECEMBER 20, 2022

Mr. LEE (for himself and Mr. BOOKER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To protect access to kratom.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Federal Clarity for Kratom Consumers Act''.

SEC. 2. ACCESS TO KRATOM.

(a) OPENNESS IN RESEARCH.—

(1) IN GENERAL.—During the period that begins 30 days after the date of enactment of this Act and ends 90 days after such date of enactment, the Secretary, acting through the Commissioner, shall

hold at least one hearing that provides an open forum for the discussion on the current scientific data and information about safety and use of products containing kratom or kratom-derived products marketed as a food, dietary ingredient, or dietary supplement.

(2) HEARING REQUIREMENTS.—The hearing under paragraph (1) shall—

(A) include input from leading scientific researchers on kratom and kratom-derived products; and

(B) consider—

(i) how many individuals in the United States consume kratom and kratom-derived products;

(ii) the scope, scale, and degree of dependence or addiction associated with kratom, mitragynine, and 7–hydroxymitragynine;

(iii) the causality of deaths in which kratom or kratom-derived products are associated, including instances in which—

(I) a kratom-containing product or kratom-derived product was con-

sumed together with legal or illegal drugs; or

(II) the kratom-containing product or kratom-derived product consumed was contaminated with a different non-drug adulterant known to endanger health;

(iv) whether use of kratom or kratom-derived products is directly linked to the use of more dangerous scheduled substances;

(v) any adverse health impacts that could be expected if kratom or kratom-derived were no longer available; and

(vi) the potential health and wellness benefits of kratom and kratom-derived products.

(3) PUBLIC DOCKET.—Not later than 30 days after the date of enactment of this Act, the Secretary shall open a public docket for submission of public comments for consideration at the hearing under paragraph (1). The Secretary shall leave such public docket open for comments for not fewer than 30 days before the hearing takes place.

(4) PUBLICATION OF INFORMATION.—The Secretary shall publish on the website of the Food and Drug Administration the transcripts of all hearings conducted pursuant to paragraph (1), subject to section 552(b) of title 5, United States Code.

(b) TASK FORCE.—

(1) ESTABLISHMENT.—Not later than 30 days after the date of enactment of this Act, the Secretary shall convene a task force, to be known as the ''Kratom Research Task Force'', to coordinate kratom-related research conducted or supported by the Federal Government.

(2) REPORTS ON KRATOM RESEARCH.—

(A) INITIAL REPORT.—Not later than 90 days after the date of enactment of this Act, the Kratom Research Task Force shall submit to Congress, the Secretary, and the Commissioner a report that details all federally funded kratom-related research that has begun or been completed prior to such date of enactment.

(B) SUBSEQUENT QUARTERLY REPORTS.—Not later than 90 days after submission of the report under subparagraph (A), and quarterly thereafter, the Kratom Research Task Force

shall submit to Congress, the Secretary, and the Commissioner a report that includes—

(i) a progress report on all federally funded kratom-related research and findings made during the applicable quarter; and

(ii) an analysis of the results of all such research.

(3) PUBLIC MEETINGS.—The Kratom Research Task Force shall convene public meetings with appropriate experts and stakeholders to increase public awareness concerning the current state of kratom-related research.

(4) PUBLICLY AVAILABLE INFORMATION.—The Secretary shall—

(A) publish the report submitted under paragraph (2)(A) on the website of the Food and Drug Administration; and

(B) update such website in accordance with the quarterly reports submitted under paragraph (2)(B), upon receipt of each such report.

(5) TERMINATION OF TASK FORCE.—On the date that is 2 years after the initial report is submitted by the Kratom Research Task Force under

paragraph (2)(A), such task force shall be terminated.

(c) PROTECTION OF KRATOM FROM CURRENT REGULATIONS.—The Secretary shall not—

(1) impose requirements on kratom or kratom-derived products that are more restrictive than the requirements for food, dietary supplements, and dietary ingredients that apply under The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

(2) treat kratom, or any product derived from or containing kratom, as an adulterated dietary supplement—

(A) for containing a new dietary ingredient as described in subparagraph (B) of section 402(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(f)(1)); or

(B) pursuant to subparagraph (C) of such section 402(f)(1); or

(3) require kratom to undergo requirements for notification as a new dietary ingredient under section 413 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350b).

(d) PROTECTION FROM FUTURE ADMINISTRATIVE ACTION.—

(1) IN GENERAL.—Any rulemaking the Secretary initiates to regulate kratom shall—

(A) comply with formal rulemaking requirements under section 552(a) of title 5, United States Code; and

(B) require public, in-person hearings.

(2) PUBLICATION OF INFORMATION.—The Secretary shall publish on the website of the Food and Drug Administration the transcripts of all hearings conducted pursuant to paragraph (1)(B), subject to section 552(b) of title 5, United States Code.

(e) IMPORT ALERT REQUIREMENTS.—The Secretary may not issue, implement, or enforce an import alert for a kratom or kratom-derived product unless the Secretary determines that there is a history of such kratom or kratom-derived product being adulterated as described in section 402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(f)(1)(A)), or evidence that such kratom or kratom-derived product is adulterated as described in such section.

(f) NONPREEMPTION.—Nothing in this section shall preempt any State law.

(g) DEFINITIONS.—In this section:

(1) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(2) COMMISSIONER.—The term ''Commissioner'' means the Commissioner of Food and Drugs.

(3) DIETARY SUPPLEMENT.—The term ''dietary supplement'' has the meaning given such term in section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)).

(4) DIETARY INGREDIENT.—The term ''dietary ingredient'' means a dietary ingredient as such term is used in section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)(1)).

(5) FOOD.—The term ''food'' has the meaning given such term in section 201(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)).

(6) KRATOM.—The term ''kratom'' means the botanical Mitragyna speciosa.

(7) NEW DIETARY INGREDIENT.—The term ''new dietary ingredient'' has the meaning given such term in section 413(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350b(d)).

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