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S.L.C.

Paul S.2292 Amendment #1

Rand Paul

AMENDMENT NO._____ Calendar No._____

Purpose: To require the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to publish a final rule relating to nonclinical testing methods.

IN THE SENATE OF THE UNITED STATES—119th Cong., 1st Sess.

S. 2292

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user fee program for over-the-counter monograph drugs, 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 Mr. PAUL

Viz:

At the appropriate place, insert the following:

SEC. __. REGULATIONS ON NONCLINICAL TESTING METHODS.

(a) INTERIM FINAL RULE.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish an interim final rule pursuant to subsections (b) and (c) to ensure implementation of the amend-

ments to section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) made by section 3209(a) of the Consolidated Appropriations Act, 2023 (Public Law 117–328; 136 Stat. 5821).

(2) EFFECTIVENESS OF INTERIM FINAL RULE.—Notwithstanding subparagraph (B) of section 553(b) of title 5, United States Code, the interim final rule issued by the Secretary of Health and Human Services under paragraph (1) shall become immediately effective as an interim final rule without requiring the Secretary of Health and Human Services to demonstrate good cause therefor.

(b) INCLUSIONS.—

(1) IN GENERAL.—The interim final rule shall replace any references to "animal" tests, data, studies, models, and research with a reference to nonclinical tests, data, studies, models, and research in the following sections of title 21, Code of Federal Regulations:

(A) Section 312.22(c).

(B) Section 312.23(a)(3)(iv).

(C) Section 312.23(a)(5)(ii).

(D) Section 312.23(a)(5)(iii).

(E) Section 312.23(a)(8).

(F) Section 312.23(a)(8)(i).

(G) Section 312.23(a)(8)(ii).

(H) Section 312.23(a)(10)(i).

(I) Section 312.23(a)(10)(ii).

(J) Section 312.33(b)(6).

(K) Section 312.82(a).

(L) Section 312.88.

(M) Section 314.50(d)(2).

(N) Section 314.50(d)(2)(iv).

(O) Section 314.50(d)(5)(i).

(P) Section 314.50(d)(5)(vi)(a).

(Q) Section 314.50(d)(5)(vi)(b).

(R) Section 314.93(e)(2).

(S) Section 315.6(d).

(T) Section 330.10(a)(2).

(U) Section 601.35(d).

(V) Any other section necessary to ensure regulatory consistency with the amendments to section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) made by section 3209(a) of the Consolidated Appropriations Act, 2023 (Public Law 117–328; 136 Stat. 5821).

(2) ADDITIONAL CHANGES.—The Secretary may make such additional changes to the sections of title 21, Code of Federal Regulations, described in

subparagraphs (A) through (V) of paragraph (1) as the Secretary determines appropriate to fully implement the replacement required under such paragraph.

(c) DEFINITION OF NONCLINICAL TEST.—The definition of "nonclinical test" in the first subsection (z) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be added to sections 312.3, 314.3, 315.2, and 601.31 of title 21, Code of Federal Regulations.