

FASTER ACT OF 2020

NOVEMBER 16, 2020.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. PALLONE, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 2117]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2117) to improve the health and safety of Americans living with food allergies and related disorders, including potentially life-threatening anaphylaxis, food protein-induced enterocolitis syndrome, and eosinophilic gastrointestinal diseases, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

CONTENTS

	Page
I. Purpose and Summary	2
II. Background and Need for the Legislation	3
III. Committee Hearings	3
IV. Committee Consideration	4
V. Committee Votes	5
VI. Oversight Findings	5
VII. New Budget Authority, Entitlement Authority, and Tax Expenditures	5
VIII. Federal Mandates Statement	5
IX. Statement of General Performance Goals and Objectives	5
X. Duplication of Federal Programs	5
XI. Committee Cost Estimate	6
XII. Earmarks, Limited Tax Benefits, and Limited Tariff Benefits	6
XIII. Advisory Committee Statement	6
XIV. Applicability to Legislative Branch	6
XV. Section-by-Section Analysis of the Legislation	6
XVI. Changes in Existing Law Made by the Bill, as Reported	7

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Food Allergy Safety, Treatment, Education, and Research Act of 2020” or the “FASTER Act of 2020”.

SEC. 2. FOOD ALLERGY SAFETY RECOMMENDATIONS OF THE NATIONAL ACADEMY OF MEDICINE.

(a) **COLLECTION OF FOOD ALLERGY DATA.**—The Public Health Service Act is amended by inserting before section 318 of such Act (42 U.S.C. 247c) the following new section:

“SEC. 317W. COLLECTION OF FOOD ALLERGY DATA.

“(a) **IN GENERAL.**—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

“(1) expand and intensify the collection of information on the prevalence of food allergies for specific allergens in the United States, such as through the National Health and Nutrition Examination Survey and the National Health Interview Survey;

“(2) include such information within annual or other periodic reporting to the Congress and the public on other surveillance activities; and

“(3) encourage research to improve the accuracy of food allergy prevalence data.

“(b) **BIOMARKERS.**—Any research conducted pursuant to subsection (a)(3) shall include—

“(1) the identification of biomarkers and tests to validate data generated from such research; and

“(2) the investigation of the use of identified biomarkers and tests in national surveys conducted as part of that research.”.

(b) **ALLERGEN LABELING.**—

(1) **MAJOR FOOD ALLERGEN DEFINITION.**—

(A) **IN GENERAL.**—Section 201(qq)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(qq)(1)) is amended by striking “and soybeans” and inserting “soybeans, and sesame”.

(B) **EFFECTIVE DATE.**—The amendment made by subparagraph (A) shall apply with respect to food introduced or delivered for introduction into interstate commerce on or after January 1, 2022.

(2) **ADDITIONAL ALLERGENS.**—Section 201(qq) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(qq)) is amended by adding at the end the following:

“(3) Any other food ingredient that the Secretary determines by regulation to be a major food allergen, based on the scientific criteria determined by the Secretary (including the prevalence and severity of allergic reactions to the food ingredient) that establish that such food ingredient is an allergen of public health concern.”.

(3) **TECHNICAL CORRECTIONS.**—Section 201(qq)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(qq)(2)) is amended by striking “paragraph” each place it appears and inserting “subparagraph”.

SEC. 3. REPORT ON USE BY FDA OF PATIENT EXPERIENCE DATA ON TREATMENTS FOR PATIENTS WITH FOOD ALLERGIES.

Section 3004 of the 21st Century Cures Act (21 U.S.C. 355 note) is amended—

(1) by striking “Not later than” and inserting the following:

“(a) **IN GENERAL.**—Not later than”; and

(2) by adding at the end the following:

“(b) **TREATMENTS FOR PATIENTS WITH FOOD ALLERGIES.**—Each report under subsection (a) shall include a synopsis of the use by the Food and Drug Administration in regulatory decisionmaking of patient experience data on products with an indication for the treatment of a food allergy.”.

I. PURPOSE AND SUMMARY

H.R. 2117, the “Food Allergy Safety, Treatment, Education, and Research Act of 2020” or the “FASTER Act of 2020”, introduced by Representative Doris O. Matsui (D-CA), aims to provide consumers and public health agencies with additional information related to food allergies. The bill would require the Centers for Disease Control and Prevention (CDC) to expand the collection of information

on specific allergens that cause food allergies and include that information in reports to Congress. The bill would also amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to include sesame as a major allergen and allow the Food and Drug Administration (FDA), through regulation, to add other food ingredients as major allergens based on the prevalence and severity of allergic reactions to the food ingredient. Additionally, the bill would require FDA to include an assessment on the use of patient experience data when making regulatory decisions on treatments for patients with food allergies in its reports on patient experience data in drug development.

II. BACKGROUND AND NEED FOR LEGISLATION

An estimated eight percent of children in the United States, which is approximately one in thirteen children, or two students in every classroom, are affected by food allergies.¹ Studies suggest that there has been a dramatic increase in children affected by allergies over the past few decades.² According to the CDC, a food allergy occurs when the body has a specific and reproducible immune response, such as anaphylaxis, to certain foods.³ Currently, the FFDCA defines major food allergens as milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans.

Although sesame is an allergen of growing concern, affecting 0.23 percent of the population of U.S. children and adults, up from 0.1 percent a decade ago, it is not required to be listed as an allergen on food packaging.⁴ In fact, in some cases, sesame may not be listed at all on ingredient labels, being referred to instead through nonspecific terms such as “flavors” or “words that may not be easily recognized by consumers as containing sesame, such as tahini”.⁵ In response to a growing concern about sesame allergy, FDA released a request for information in 2018, seeking comment on the prevalence and severity of sesame allergies and the prevalence of sesame-containing foods in the United States.⁶

FDA has not taken any additional action to list sesame as a major allergen since that time. Given the growing concern around sesame and other food allergens, legislation is necessary to list sesame as a major food allergen and streamline processes at FDA to add additional food allergens based on the latest science and clinical evidence.

III. COMMITTEE HEARINGS

For the purposes of section 103(i) of H. Res. 6 of the 116th Congress, the following hearing was used to develop or consider H.R. 2117:

¹Centers for Disease Control and Prevention, *Food Allergies* (May 29, 2019) (www.cdc.gov/healthyschools/foodallergies/index.htm).

²Jennifer Protudjer and Elissa Abrams, *Sesame the New Priority Allergen?*, JAMA Network Open (Aug. 2, 2019) (jamanetwork.com/journals/jamanetworkopen/fullarticle/2740776).

³Response Letter from FDA, to Lassman Law + Policy (Nov. 7, 2019) (www.regulations.gov/document?D=FDA-2019-P-1679-0079).

⁴Christopher M. Warren et al., *Prevalence and Severity of Sesame Allergy in the United States*, JAMA Network Open (Aug. 2, 2019) (jamanetwork.com/journals/jamanetworkopen/fullarticle/2740786).

⁵*Id.*

⁶Food and Drug Administration, *FDA Asks for Input on Sesame Allergies and Food Labeling* (Oct. 29, 2018) (www.fda.gov/food/cfsan-constituent-updates/fda-asks-input-sesame-allergies-and-food-labeling).

The Subcommittee on Health held a legislative hearing on January 29, 2020, entitled, “Improving Safety and Transparency in America’s Food and Drugs.” The hearing focused on H.R. 2117 and nine other bills. The Subcommittee received testimony from the following witnesses:

Panel I:

- Jeff Allen, Ph.D., President and CEO, Friends of Cancer Research.
- Richard Kaeser, Vice President, Global Brand Protection, Johnson & Johnson.
- Fernando Muzzio, Ph.D., Distinguished Professor, Chemical and Biochemical Engineering, Rutgers, the State University of New Jersey.
- Kao-Ping Chua, M.D., Ph.D., Assistant Professor, Department of Pediatrics, University of Michigan Medical School.

Panel II:

- Melanie Benesh, Legislative Attorney, Environmental Working Group.
- Tom Balmer, Executive Vice President, National Milk Producers Federation.
- J. David Carlin, Senior Vice President of Legislative Affairs and Economic Policy, International Dairy Foods Association.
- Douglas Corey, D.V.M., Past President, American Association of Equine Practitioners.
- Talia Day, Patient Advocate.
- Paul C. DeLeo, Ph.D., Principal, Integral Consulting, Inc.
- Mardi Mountford, President, Infant Nutrition Council of America.
- Nancy Perry, Senior Vice President, Government Relations, American Society for the Prevention of Cruelty to Animals.
- Sara Sorscher, Deputy Director of Regulatory Affairs, Center for Science in the Public Interest.

IV. COMMITTEE CONSIDERATION

Representative Matsui introduced H.R. 2117 on April 8, 2019, and the bill was referred to the Committee on Energy and Commerce. H.R. 2117 was then referred to the Subcommittee on Health on April 9, 2019. The Subcommittee held a legislative hearing on the bill on January 29, 2020.

The Subcommittee met in open markup session on March 11, 2020, pursuant to notice, to consider H.R. 2117 and twelve other bills. During consideration of the bill, an amendment in the nature of a substitute offered by Ms. Matsui was agreed to by a voice vote. Upon conclusion of consideration of the bill, the Subcommittee agreed to forward H.R. 2117 favorably to the full Committee, amended, by a voice vote, a quorum being present.

On July 15, 2020, the full Committee met in virtual open markup session, pursuant to notice, to consider a committee print of H.R. 2117 as amended by the Subcommittee on Health on March 11, 2020, and twenty-nine other bills. No amendments were offered during consideration of the bill. Upon conclusion of its consider-

ation, the full Committee agreed to a motion on final passage by Mr. Pallone, Chairman of the committee, to order H.R. 2117 reported favorably to the House, as amended, by a voice vote, a quorum being present.

V. COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that there were no record votes taken on H.R. 2117, including the motion for final passage of the bill.

VI. OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

VII. NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

VIII. FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

IX. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to improve the health and safety of Americans living with food allergies and related disorders and streamline processes at the FDA.

X. DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 2117 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111-139 or the most recent Catalog of Federal Domestic Assistance.

XI. COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

XII. EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 2117 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIII. ADVISORY COMMITTEE STATEMENT

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

XIV. APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

XV. SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

SEC. 1. Short title

Section 1 designates that the short title may be cited as the “Food Allergy Safety, Treatment, Education, and Research Act of 2020” or the “FASTER Act of 2020”.

SEC. 2. Food allergy safety recommendation of the National Academy of Medicine

Subsection (a) of section 2 amends the Public Health Service Act by inserting before section 318 a new section on the Collection of Food Allergy Data. This new section requires the Secretary of Health and Human Services (the Secretary), acting through the Director of the CDC, to (1) expand and intensify the collection of information on the prevalence of food allergies for specific allergens in the United States, such as through the National Health and Nutrition Examination Survey and the National Health Interview Survey; (2) include such information within annual or other periodic reporting to Congress and the public; and (3) encourage research to improve the accuracy of food allergy prevalence data. Any research conducted under this section is required to include the identification of biomarkers and tests that can be used to validate data generated from such research and the investigation of the use of identified biomarkers and tests in national surveys conducted as part of that research.

Subsection (b) of section 2 amends the FFDCA to add sesame as a major food allergen and sets the effective date of this amendment as January 1, 2022. Subsection (b) also amends the FFDCA to allow the Secretary, through regulation, to add additional food allergens to the list of major food allergens based on the scientific criteria determined by the Secretary (including the prevalence and se-

verity of allergic reactions to the food ingredient) that establish that such food ingredient is an allergen of public health concern. Finally, subsection (b) makes a technical correction to the FFDCA.

SEC. 3. Report on use by FDA of patient experience data on treatments for patients with food allergies

Section 3 amends the 21st Century Cures Act to require that a report on patient experience data in drug development must include a synopsis of the use by FDA in regulatory decision making of patient experience data on products with an indication for the treatment of a food allergy.

XVI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART B—FEDERAL-STATE COOPERATION

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SEC. 317W. COLLECTION OF FOOD ALLERGY DATA.

(a) *IN GENERAL.*—*The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—*

(1) *expand and intensify the collection of information on the prevalence of food allergies for specific allergens in the United States, such as through the National Health and Nutrition Examination Survey and the National Health Interview Survey;*

(2) *include such information within annual or other periodic reporting to the Congress and the public on other surveillance activities; and*

(3) *encourage research to improve the accuracy of food allergy prevalence data.*

(b) *BIOMARKERS.*—*Any research conducted pursuant to subsection (a)(3) shall include—*

(1) *the identification of biomarkers and tests to validate data generated from such research; and*

(2) *the investigation of the use of identified biomarkers and tests in national surveys conducted as part of that research.*

* * * * *

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a)(1) The term “State”, except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term “Territory” means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term “interstate commerce” means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term “Department” means the Department of Health and Human Services.

(d) The term “Secretary” means the Secretary of Health and Human Services.

(e) The term “person” includes individual, partnership, corporation, and association.

(f) The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term “drug” means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term “counterfeit drug” means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) The term “device” (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to

evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q)(1)(A) Except as provided in clause (B), the term "pesticide chemical" means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide. Notwithstanding any other provision of law, the term "pesticide" within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.

(B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):

(i) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is applied for such use on food, or the substance is included for such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is included for such use in water that comes into contact with the commodity, as follows:

(I) The substance is applied in the field.

(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

(ii) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is a food contact substance as defined in section 409(h)(6), and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that

has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

With respect to the definition of the term “pesticide” that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act, this clause does not exclude any substance from such definition.

(2) The term “pesticide chemical residue” means a residue in or on raw agricultural commodity or processed food of—

(A) a pesticide chemical; or

(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

(3) Notwithstanding subparagraphs (1) and (2), the Administrator may by regulation except a substance from the definition of “pesticide chemical” or “pesticide chemical residue” if—

(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this Act other than sections 402(a)(2)(B) and 408.

(r) The term “raw agricultural commodity” means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term “food additive” means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

- (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or
- (2) a pesticide chemical; or
- (3) a color additive; or
- (4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following);
- (5) a new animal drug; or
- (6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

(t)(1) The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "safe," as used in paragraph (s) of this section and in sections 409, 512, 571, and 721, has reference to the health of man or animal.

(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been

used to a material extent or for a material time under such conditions.

Provided that any drug intended for minor use or use in a minor species that is not the subject of a final regulation published by the Secretary through notice and comment rulemaking finding that the criteria of paragraphs (1) and (2) have not been met (or that the exception to the criterion in paragraph (1) has been met) is a new animal drug.

(w) The term “animal feed”, as used in paragraph (w) of this section, in section 512, and in provisions of this Act referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(x) The term “informal hearing” means a hearing which is not subject to section 554, 556, or 557 of title 5 of the United States Code and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer’s report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer’s report of the hearing.

(y) The term “saccharin” includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(z) The term “infant formula” means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(aa) The term “abbreviated drug application” means an application submitted under section 505(j) for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and—

(1) in the case of section 306, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of sections 307 and 308, includes any supplement to such an application.

(bb) The term “knowingly” or “knew” means that a person, with respect to information—

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(cc) For purposes of section 306, the term “high managerial agent”—

(1) means—

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for—

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product.

(dd) For purposes of sections 306 and 307, the term “drug product” means a drug subject to regulation under section 505, 512, or 802 of this Act or under section 351 of the Public Health Service Act.

(ee) The term “Commissioner” means the Commissioner of Food and Drugs.

(ff) The term “dietary supplement”—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that—

(A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or

(ii) complies with section 411(c)(1)(B)(ii);

- (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
 - (C) is labeled as a dietary supplement; and
- (3) does—

(A) include an article that is approved as a new drug under section 505 or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and

(B) not include—

(i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

Except for purposes of sections 201(g) and 417, a dietary supplement shall be deemed to be a food within the meaning of this Act.

(gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

(hh) The term "Administrator" means the Administrator of the United States Environmental Protection Agency.

(ii) The term "compounded positron emission tomography drug"—

(1) means a drug that—

(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

(jj) The term "antibiotic drug" means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chlor-

amphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

(kk) PRIORITY SUPPLEMENT.—The term “priority supplement” means a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (111 Stat. 2298).

(ll)(1) The term “single-use device” means a device that is intended for one use, or on a single patient during a single procedure.

(2)(A) The term “reprocessed”, with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.

(B) A single-use device that meets the definition under clause (A) shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term “recycled” rather than the term “reprocessed”.

(3) The term “original device” means a new, unused single-use device.

(mm)(1) The term “critical reprocessed single-use device” means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

(2) The term “semi-critical reprocessed single-use device” means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(nn) The term “major species” means cattle, horses, swine, chickens, turkeys, dogs, and cats, except that the Secretary may add species to this definition by regulation.

(oo) The term “minor species” means animals other than humans that are not major species.

(pp) The term “minor use” means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

(qq) The term “major food allergen” means any of the following:

(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, [and soybeans] *soybeans, and sesame.*

(2) A food ingredient that contains protein derived from a food specified in [paragraph] *subparagraph* (1), except the following:

(A) Any highly refined oil derived from a food specified in [paragraph] *subparagraph* (1) and any ingredient derived from such highly refined oil.

(B) A food ingredient that is exempt under [paragraph] *subparagraph* (6) or (7) of section 403(w).

(3) Any other food ingredient that the Secretary determines by regulation to be a major food allergen, based on the scientific criteria determined by the Secretary (including the prevalence and severity of allergic reactions to the food ingredient) that establish that such food ingredient is an allergen of public health concern.

(rr)(1) The term “tobacco product” means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

(2) The term “tobacco product” does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 503(g).

(3) The products described in paragraph (2) shall be subject to chapter V of this Act.

(4) A tobacco product shall not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).

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21ST CENTURY CURES ACT

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DIVISION A—21ST CENTURY CURES

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TITLE III—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

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SEC. 3004. REPORT ON PATIENT EXPERIENCE DRUG DEVELOPMENT.

[Not later than] (a) *IN GENERAL.*—Not later than June 1 of 2021, 2026, and 2031, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall prepare and publish on the Internet website of the Food and Drug Administration a report assessing the use of patient experience data in regulatory decisionmaking, in particular with respect to the review of patient experience data and information on patient-focused drug development tools as part of applications approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(b) *TREATMENTS FOR PATIENTS WITH FOOD ALLERGIES.*—Each report under subsection (a) shall include a synopsis of the use by the Food and Drug Administration in regulatory decisionmaking of pa-

tient experience data on products with an indication for the treatment of a food allergy.

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