THE THRIVE ACT OF 2026

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This Act may be cited as the "Therapeutic Healthspan Research, Innovation, and Validation Enhancement Act of 2026" or the "THRIVE Act of 2026."

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SECTION 2. FINDINGS

(A) FINDINGS — Congress finds that:

(1) Chronic diseases are the leading cause of death and disability in the United States, placing a significant burden on individuals, families, and the healthcare system.

(2) Life expectancy in the United States has declined sharply over the past decade and lags significantly behind peer nations, with substantial disparities between income levels as well as between urban and rural populations.

(3) Early intervention and prevention strategies that target the underlying biological processes of aging and chronic diseases hold promise for improving healthspan—the period of life free of age-related chronic diseases and disabilities.

(4) Current healthcare and pharmaceutical business models prioritize treatment of acute conditions over prevention, lacking strong incentives to invest in preventive therapies and population health improvement.

(5) Equitable access to preventive health products is essential for promoting healthcare equity and reducing disparities in chronic disease burden.

(6) The current regulatory framework under the Food, Drug, and Cosmetic Act (FD&C Act) emphasizes the development and approval of treatments for manifested diseases—one disease at a time—over the development and approval of products aimed at preventing multiple age-related chronic diseases and some common forms of cancers.

(7) Enabling access to safe and effective interventions that can extend the period of healthy, independent living would provide significant benefits for individuals, society, and the economy.

(8) Developing and evaluating the evidence to support healthspan products and claims is inherently more complex than assessing the safety and effectiveness of drugs for treating specific, established diseases.

(9) Healthspan is a multifaceted, long-term outcome that can be influenced by many factors beyond the drug's direct effects.

(10) Given these complexities, encouraging and incentivizing innovation in this area is crucial for promoting the overall health and well-being of the nation.

SECTION 3. PURPOSE

(A) IN GENERAL The purpose of this Act is to establish a regulatory framework to support, incentivize, and oversee the development of products regulated by the Food and Drug Administration ("FDA") that are intended to lengthen healthspan, the period of life free from the chronic diseases and conditions responsible for most mortality and disability in the general population.

(B) BACKGROUND — By age 65, most people have begun to experience multiple chronic health conditions, as well as functional and cognitive decline. These conditions adversely affect the ability to withstand infection or recover from other health threats, as demonstrated by the high mortality rate among older individuals and the chronically ill during the COVID-19 pandemic. By increasing healthspan, many of the economic and societal burdens of disease and frailty can be reduced, allowing individuals to remain self-sufficient longer with less pain, suffering, debilitating loss of function, and dependency on acute and chronic medical care. Advances in the study of aging biology strongly support the prospects of identifying and targeting the shared root causes of age-related chronic diseases and certain forms of cancer. The quest to convert this science into evidence-based solutions for people of all ages presents a daunting challenge. The enormous time and costs inherent in achieving definitive evidence of effectiveness for such interventions impede investment in and development of these potential solutions.

(C) NEED FOR NEW FRAMEWORK —

(1) The current regulatory framework for the approval of new drugs and biologics is well-suited for products that treat a disease or condition after onset. Prevention under the current framework is similarly focused on addressing one disease at a time, usually after well-known markers of the disease have been detected. A regulatory framework that is complementary to, but which does not alter the existing framework, is needed for products specifically intended to prevent or reverse the risks of multiple chronic diseases and disabilities among the general or pre-disease populations. This need arises from the significantly greater time and costs required to develop interventions aimed at preventing multiple chronic diseases compared to those for treating a single disease.

(2) The general approach to preempting multiple diseases may include developing new therapeutics, repurposing older products, providing an evidence-based pathway for dietary supplements, and studying innovative combinations of products to delay the onset of chronic conditions or slow their progression. It may also include the use of wearable devices, passive monitoring systems, and other medical device technologies to track subclinical indicators of disease. Medical devices enabled by artificial intelligence hold the potential to guide behavior and interventions that can help individuals maintain or

even improve their health and avert or slow progression toward chronic disease. Artificial intelligence platforms may identify new endpoints, including molecular biomarkers, to support the development of drugs, devices, and nutritional products to lengthen healthspan and foster a healthier and more resilient population.

(D) NEW REGULATORY PATHWAY —

(1) The THRIVE Act establishes a tiered system for healthspan claims and approvals, each with clearly defined standards for evidence, including the following tiers for healthspan drugs and biological products:

(a) Tier 1: Requires sufficient evidence that a product is **reasonably likely** to increase healthspan, based on a combination of data types (e.g., mechanistic studies, *in silico/in vitro* models of cellular aging, advanced imaging, animal models, clinical trial experience, biomarker data, epidemiologic and real-world studies) demonstrating that the reasonably likely benefit of increased healthspan outweighs known safety risks.

(b) Tier 2: Requires intermediate clinical evidence from clinical trials of specific durations and other studies, showing that a product is **likely** to increase healthspan in a defined population. It must demonstrate that the benefits continue to outweigh the risks.

(c) Tier 3: Requires **substantial evidence of effectiveness**, including data from well-controlled studies and diverse population representation that demonstrate long-term benefits and safety. These standards balance the need for robust and comprehensive evidence with the practical considerations of developing and approving healthspan products, providing a structured pathway that encourages innovation while ensuring safety and efficacy.

(2) The THRIVE Act establishes new administrative processes to enhance the development of healthspan products:

(a) Center for Healthspan Products: Establishes a cross-agency Center to facilitate, coordinate, and conduct reviews; provide expertise in aging biology and biomarkers; develop guidance documents; and facilitate stakeholder coordination.

(b) Healthspan Product Development Meetings: Introduces structured meeting types—Type H meetings—between sponsors and the Secretary to discuss development programs, novel endpoints, study designs, evidence generation, and to obtain feedback.

(c) Breakthrough Healthspan Product Designation: Allows sponsors to request a designation for breakthrough healthspan products, triggering expedited development and

review processes if the product meets specific criteria. These processes are designed to streamline the development, review, and approval of healthspan products, encouraging innovation while ensuring regulatory oversight and evidence-based claims.

(3) The THRIVE Act provides incentives designed to encourage the development of healthspan products, including:

(a) Earlier Market Access: Tier 1 and Tier 2 approvals allow healthspan drugs and devices to access the market earlier than they would otherwise be able to under current pathways.

(b) Healthspan Claim Exclusivity: Sponsors that secure approval for healthspan claims are granted exclusivity rights, ensuring that the holder of such approval shall have the exclusive right to make healthspan claims for the approved ingredient(s) or combination of ingredients, or in the case of medical devices, those with the same or substantially similar purpose, mechanism, effect, and performance characteristics, during the exclusivity period. The Act provides the holders of healthspan claim exclusivity with the remedy to pursue civil action against any entity violating this exclusivity.

(c) Transferable Priority Review Vouchers: Sponsors will be eligible to receive a transferable priority review voucher for their first Tier 3 healthspan drug approval in the case of large companies, or for their first Tier 2 healthspan drug approval in the case of emerging companies. These approvals must target at least two Major Age-Related Chronic Diseases, or alternatively, the voucher may be granted for Tier 3 approval of a drug that has received a Breakthrough Healthspan Drug designation. A transferable healthspan priority review voucher may be applied to any application held by the sponsor, or the sponsor may transfer the voucher for use by any third party.

(d) Exclusivity Enhancements: Products that demonstrate significant healthspan benefits may receive additional exclusivity, such as "Prevention Impact Exclusivity" or "Population Health Exclusivity," to incentivize developers to focus on preventive measures and population health outcomes.

(e) Healthspan Innovation Prizes: Up to five substantial prizes of $100,000,000 each are available for products that **substantially** reduce the risks of or reverse major age-related chronic diseases and are cost-effective compared to standard interventions. This serves as a significant incentive to innovate in the field of preventive or rejuvenative healthcare.

(4) The THRIVE Act does not in any way alter or replace the existing regulations and procedures that apply to developing and marketing products for disease-related

indications. Nor does the Act obligate any sponsor or manufacturer to pursue a healthspan claim. Instead, the Act is intended to supplement current regulations and procedures with optional pathways for pursuing healthspan indications or claims for drugs and biologics, medical devices, dietary supplements, and foods.

(E) SCOPE — Pursuant to the THRIVE Act of 2026, preempting multiple chronic diseases may include:

(1) Development of new therapeutics

(2) Repurposing of older products or repositioning investigational products for healthspan indications

(3) Making of evidence-based healthspan claims for dietary supplements

(4) Study of innovative combinations of products

(5) Use of wearables and passive monitoring systems

(6) Medical device technologies to track subclinical indicators of disease

(7) Medical devices enhanced by artificial intelligence

(8) Development of predictive biomarkers and surrogate endpoints

SECTION 4. HEALTHSPAN PRODUCTS

SEC. [555(a)]. HEALTHSPAN PRODUCTS. This section establishes a comprehensive framework for the development and approval of healthspan products, ensuring that these products are evaluated based on their ability to enhance healthspan in defined populations.

(A) DEFINITIONS — For purposes of this section:

(1) The term "healthspan" means the period of life free from age-related chronic diseases and/or disabilities, as strategically targeted by interventions to reduce risks and delay onset.

(2) The term "increases healthspan" means prevents[1] or reverses[2] multiple (i.e., two or more) major age-related chronic diseases and/or disabilities based on a demonstrated effect on the biology of aging.

(3) The term "major age-related chronic diseases" means, for purposes of this Act, disease that may be prevented or reversed based on a showing of an effect on the biology of aging, and may include:

(a) Cardiovascular disease

(b) Type 2 diabetes

(c) Metabolic Dysfunction-Associated Steatohepatitis (MASH)

(d) Some forms of cancer

(e) Parkinson's disease, dementia, and Alzheimer's disease

(f) Frailty, including osteoporosis and age-related loss of muscle mass and function

(g) Ocular conditions such as cataracts and macular degeneration, and other sensory conditions such as hearing loss

(4) The term "healthspan drug" means a drug, as defined in Section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)), or a biological product, as defined in Section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)), that is intended to increase healthspan. The term "healthspan drug" includes drugs previously approved under Section 505 of the FD&C Act for non-healthspan uses, repurposed drugs, and drugs consisting of new molecular entities not previously approved under Section 505 of the FD&C Act.

(5) The term "healthspan food" means a food, as defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)), that is intended to improve healthspan. Claims regarding healthspan food may be made as a qualified health claim under existing law.

(6) The term "healthspan dietary supplement" means a dietary supplement, as defined in the Dietary Supplement Health and Education Act of 1994, that is intended to improve healthspan.

[1]Prevent also means reducing the risk of or slowing the onset of two or more chronic diseases.
[2]Reverses means restoring to a condition free of two or more chronic diseases.

(7) The term "healthspan device" means a device, as defined in section 201(h)(1) of the FD&C Act (21 U.S.C. 321(h)(1)), that is intended to improve healthspan.

(8) The term "healthspan indication" means a description of the benefit that the product has been shown or is likely to provide. This benefit is typically described as the prevention or reversal of two or more age-related chronic diseases and/or disabilities.

(9) The term "healthspan product" means a healthspan drug, device, food, or healthspan dietary supplement that has been approved or authorized as a healthspan product under this section.

(10) The term "human drug application" means an application submitted under section 505(b) of the Act or an application for licensure of a biological drug product under section 351 of the Public Health Service Act.

(11) The term "general adult population" means the United States population aged eighteen years and older who are free of chronic diseases and obesity. Reasonable exclusions, such as pregnant individuals, may apply.

(12) The term "defined population" means a specified subset of the general adult population from which evidence supporting a healthspan indication is drawn.

(13) The term "Tier 1 healthspan product" means a healthspan product that has been shown, based on sufficient scientific and early clinical evidence, to be reasonably likely to increase healthspan in a defined population.

(14) The term "Tier 2 healthspan product" means a healthspan product that has been shown, based on intermediate clinical evidence, to be likely to increase healthspan in a defined population.

(15) The term "Tier 3" healthspan product means a healthspan product that has been demonstrated, based on substantial evidence of effectiveness, to increase healthspan in a defined population.

(16) The term "early clinical evidence" means evidence from human pharmacologic studies and clinical trials of 10 weeks' duration or longer, which, combined with other forms of evidence, is persuasive to experts that a product is reasonably likely to increase healthspan.

(17) The term "intermediate clinical evidence" means evidence from one or more clinical trials of 26 weeks' duration or longer, which, either alone or in combination with

other forms of evidence, is persuasive to experts that a product is reasonably likely to increase healthspan.

(18) The term "substantial evidence" of effectiveness, regarding healthspan drugs and healthspan dietary supplements, will carry the same meaning as defined in Sections 505(d) and (e) of the Food, Drug, and Cosmetic Act.

(B) REGULATION —

(1) To the extent not contrary to this section [555], healthspan products will be subject to regulation under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, as applicable.

(2) The Secretary of Health and Human Services may establish, by regulation:

(a) requirements for the approval, suspension, and withdrawal of healthspan food, drug, and device applications;

(b) relevant postmarketing requirements; and

(c) marketing and promotional limitations for all healthspan products.

(C) HEALTHSPAN DRUG —

(1) **SAFETY STANDARD FOR APPROVAL** — For each tier of healthspan marketing approval, a healthspan drug, which may be an approved new drug or a new drug that has not previously received marketing approval, must be found to be safe for use under the conditions prescribed, recommended, or suggested in the labeling of the product. This determination must be supported by safety testing and available data (including the history of use of the ingredient(s)) commensurate with the applicable healthspan tier of approval.

(2) **EVIDENTIARY STANDARD FOR APPROVAL** —

(a) Tier 1 — To obtain and maintain approval for a Tier 1 healthspan drug, a sponsor must:

(i) present sufficient evidence that the drug appears reasonably likely to increase healthspan in a defined population;

(ii) demonstrate that the reasonably likely benefit of increased healthspan, including the magnitude of such benefit in the defined population, is sufficient to outweigh the safety risks associated with the use of the drug; and

(iii) commence clinical studies agreed upon with the Center for Healthspan Products for the generation of evidence to apply for Tier 2 approval by the second anniversary of such Tier 1 approval.

(iv) Sufficient evidence may consist of at least one clinical trial of six (6) months or longer and a combination of data from digital or mechanistic, in silico/in vitro models of cellular aging, animal models, clinical, epidemiologic, and real-world studies, some or all of which, taken together, are reasonably likely to predict a healthspan benefit.

(v) Clinically relevant healthspan endpoints may include endpoints based on biomarkers, surrogates, or measures of physical movement, cognitive, and/or immunologic function.

(vi) The indication of a product that fails to maintain Tier 1 healthspan approval shall be withdrawn or, provided the drug continues to be considered safe for use, modified to appropriately state the limitation of available evidence to support the indication.

(b) Tier 2 — To maintain Tier 1 approval and obtain approval as a Tier 2 healthspan drug, on or before five years on the market, the sponsor must:

(i) provide intermediate clinical evidence demonstrating that the drug is likely to increase healthspan in a defined population;

(ii) demonstrate the likely benefit to healthspan in such a defined population, including the magnitude of such improvement, continues to outweigh risks suggested by the accumulated safety data from the intended patient population; and

(iii) commence clinical studies agreed upon with the Center for Healthspan Products for the generation of evidence to apply for a Tier 3 approval by the second anniversary of such Tier 2 approval.

(iv) Intermediate clinical evidence may include data from randomized, controlled clinical trials of at least two years' duration or alternative study designs showing statistically significant effects on healthspan biomarkers or surrogate endpoints likely to predict healthspan benefit, or composite endpoints that do not show consistent effects across components.

(v) The indication of a product that fails to gain Tier 2 healthspan approval shall be withdrawn or, provided the drug continues to be considered safe for use,

modified to appropriately state the limitation of available evidence to support the indication.

(c) Tier 3 — To maintain Tier 2 approval and obtain approval as a Tier 3 healthspan drug, on or before ten years on the market, the sponsor must:

(i) demonstrate with substantial evidence of effectiveness, including adequate and well-controlled studies, that the drug increases healthspan in a defined population; and

(ii) demonstrate the benefit to healthspan in such a defined population, including the magnitude of such improvement, continues to outweigh risks suggested by the accumulated safety data from the intended patient population.

(iii) A Tier 3 healthspan drug shall be considered approved without further requirements for providing evidence in support of the approved healthspan claims.

(iv) The indication of a product that fails to gain Tier 3 healthspan approval shall be withdrawn or, provided the drug continues to be considered safe for use, modified to appropriately state the limitation of available evidence to support the indication.

(3) **ENHANCED PHARMACOVIGILANCE AND REGISTRY REQUIREMENT**

(a) For Tier 1 approval, the sponsor may be required to:

(i) submit and obtain approval for a registry protocol and/or an active surveillance plan;

(ii) monitor for adverse events of special interest; and

(iii) submit periodic safety updates that will typically exceed, in frequency, those required for products approved for disease indications.

(b) For Tier 2 approval, the sponsor may be required to:

(i) develop and obtain approval of an active surveillance plan;

(ii) monitor for adverse events of special interest; and

(iii) submit periodic safety updates that may exceed those required for products approved for disease indications.

(D) HEALTHSPAN DEVICE —

(1) **SAFETY STANDARD FOR APPROVAL** — For each tier of healthspan marketing approval, a healthspan device must be found to be safe for use under the conditions prescribed, recommended, or suggested in the labeling of the product, supported by safety testing commensurate with the applicable healthspan tier of approval.

(2) **EVIDENTIARY STANDARD FOR APPROVAL** —

(a) Tier 1 — To obtain and maintain approval for a Tier 1 healthspan device, a sponsor must:

(i) present sufficient evidence that the physiological or behavioral effects of the device are consistent with and supportive of increasing healthspan in a defined population;

(ii) demonstrate that the reasonably likely benefit of increased healthspan, including the magnitude of such benefit in the defined population, is acceptable in light of known safety risks associated with the use of the device or, in the case of a healthspan device that is a diagnostic or predictive test, present evidence that supports the product's utility for reliably providing information or feedback that will substantially help to increase healthspan; and

(iii) commence clinical studies agreed upon with the Center for Healthspan Products for the generation of evidence to apply for Tier 2 approval by the second anniversary of such Tier 1 approval.

(v) The indication of a product that fails to maintain Tier 1 healthspan approval shall be withdrawn or, provided the device continues to be considered safe for use, modified to appropriately state the limitation of available evidence to support the indication.

(b) Tier 2 — To maintain Tier 1 approval and obtain approval as a Tier 2 healthspan device, on or before five years on the market, the sponsor must:

(i) provide intermediate clinical evidence that the device likely improves healthspan in a defined population;

(ii) demonstrate that the improvement in healthspan in such a defined population, including the magnitude of such improvement, is acceptable in light of known safety concerns associated with the use of the device; and

(iii) commence clinical studies agreed upon with the Center for Healthspan Products for the generation of evidence to apply for a Tier 3 approval by the second anniversary of such Tier 2 approval.

(iv) The indication of a product that fails to maintain Tier 2 healthspan approval shall be withdrawn or, provided the device continues to be considered safe for use, modified to appropriately state the limitation of available evidence to support the indication.

(c) Tier 3 — To maintain Tier 2 approval and obtain approval as a Tier 3 healthspan device, after ten years on the market, the sponsor must:

(i) demonstrate that there is reasonable assurance of the effectiveness of the device for its healthspan intended use, including one or more adequate and well-controlled studies showing that the device materially increases healthspan, or materially enhances the development or utility of healthspan drugs or healthspan dietary supplements, in a defined adult population; and

(ii) demonstrate that such improvement, including the magnitude of such improvement, is sufficient considering known safety concerns associated with the use of the device in the general or a defined adult population.

(iii) A Tier 3 healthspan device shall be considered to be approved without further requirements for providing evidence in support of the approved healthspan claims.

(3) **CONFORMITY WITH EXISTING DEVICE CLASSES**. The Secretary shall establish, as deemed necessary, additional standards for Tier 1, Tier 2, and Tier 3 approvals of healthspan devices consistent with the clearance or approval requirements for Class II 510(k) and Class III de novo and PMA approval.

(4) **POST-MARKET REPORTING, ENHANCED PHARMACOVIGILANCE, AND REGISTRY REQUIREMENT** —

(a) Manufacturers making healthspan claims must:

(i) maintain records of all complaints and adverse events;

(ii) promptly report serious adverse events;

(iii) conduct post-market surveillance as appropriate for the product; and

(iv) submit annual reports summarizing safety and effectiveness data.

(b) For Tier 1 approval, the sponsor may be required to:

(i) submit and obtain approval for a registry protocol and/or an active surveillance plan;

(ii) monitor for adverse events of special interest; and

(iii) submit periodic safety updates that will typically exceed in frequency those required for products approved for disease indications.

(c) For Tier 2 approval, the sponsor may be required to:

(i) develop and obtain approval of an active surveillance plan;

(ii) monitor for adverse events of special interest; and

(iii) submit periodic safety updates that may exceed those required for products approved for disease indications.

(E) HEALTHSPAN FOOD — Evidence that a food, as defined in section 201(f) of the Act (21 U.S.C. 321(f)), may increase healthspan can be submitted to the Secretary. Healthspan food claims can be achieved as a qualified health claim under existing law and processes.

(F) HEALTHSPAN DIETARY SUPPLEMENT[3] —

(1) **SAFETY STANDARD FOR APPROVAL** — For each tier of healthspan marketing approval, a healthspan dietary supplement must be found to be safe for use under the conditions prescribed, recommended, or suggested in the labeling of the product, supported by safety testing and available data (including the history of use of the ingredient(s)) commensurate with the applicable healthspan tier of approval.

(2) **EVIDENTIARY STANDARD FOR APPROVAL —**

(a) Tier 1 — To obtain and maintain approval for a Tier 1 healthspan dietary supplement, a sponsor must:

(i) present sufficient evidence that the supplement appears reasonably likely to increase healthspan in a defined population;

[3]Dietary supplements are defined, regulated, and will continue to be marketed without any change under the provisions of the Dietary Supplement Health and Education Act of 1994. The THRIVE Act provides the option for a dietary supplement to be developed as a *healthspan dietary supplement*, but this entails procedures, data expectations, and product labeling similar to those for healthspan drugs.

(ii) demonstrate that the reasonably likely benefit of increased healthspan, including the magnitude of such benefit in such a defined population, is sufficient to outweigh the safety risks associated with use of the supplement;

(iii) commence clinical studies agreed upon with the Center for Healthspan Products for the generation of evidence to apply for a Tier 2 approval by the second anniversary of such Tier 1 approval;

(iv) provide sufficient evidence, which may consist of a combination of data from digital or mechanistic, *in silico or in vitro* models of cellular aging, animal models, clinical studies, epidemiologic studies, and real-world studies, some or all of which, taken together, are reasonably likely to predict a healthspan benefit; and

(v) identify clinically relevant healthspan endpoints, which may include endpoints based on biomarkers, surrogates, or measures of physical movement, cognitive function, and/or immunologic function.

(vi) The indication of a product that fails to maintain Tier 1 healthspan approval shall be withdrawn or, provided the dietary supplement continues to be considered safe for use, modified to appropriately state the limitations of available evidence to support the indication. A modified indication would require that.

(b) Tier 2 — To maintain Tier 1 approval and obtain approval as a Tier 2 healthspan dietary supplement, on or before five years on the market, the sponsor must:

(i) provide intermediate clinical evidence demonstrating that the supplement is likely to increase healthspan in a defined population;

(ii) demonstrate that the likely benefit on healthspan in such a defined population, including the magnitude of such improvement, continues to outweigh risks suggested by the accumulated safety data from the intended patient population; and

(iii) commence clinical studies agreed upon with the Center for Healthspan Products for the generation of evidence to apply for Tier 3 approval by the second anniversary of Tier 2 approval.

(iv) Intermediate clinical evidence may include data from randomized, controlled clinical trials of at least two years' duration, or alternative study designs showing statistically significant effects on healthspan biomarkers or surrogate endpoints likely to predict healthspan benefits, or composite endpoints that do not show consistent effects across components.

(v) The indication of a product that fails to gain Tier 2 healthspan approval shall be withdrawn or, provided the supplement continues to be considered safe for use, modified to appropriately state the limitation of available evidence to support the indication.

(c) Tier 3 — To maintain Tier 2 approval and obtain approval as a Tier 3 healthspan dietary supplement, on or before ten years on the market, the sponsor must:

(i) demonstrate, with substantial evidence of effectiveness, including adequate and well-controlled studies, that the supplement increases healthspan in a defined population; and

(ii) demonstrate that the benefit on healthspan in such a defined population, including the magnitude of such improvement, continues to outweigh risks suggested by the accumulated safety data from the intended patient population.

(iii) A Tier 3 healthspan dietary supplement shall be considered to be approved without further requirements for providing evidence in support of the approved healthspan claims.

(iv) The indication of a product that fails to gain Tier 3 healthspan approval shall be withdrawn or, provided the supplement continues to be considered safe for use, modified to appropriately state the limitation of available evidence to support the indication.

(3) **POST-MARKET REPORTING, ENHANCED PHARMACOVIGILANCE, AND REGISTRY REQUIREMENT** —

(a) Manufacturers making healthspan claims must:

(i) maintain records of all complaints and adversities;

(ii) promptly report serious adverse events;

(iii) conduct post-market surveillance as appropriate for the product; and

(iv) submit annual reports summarizing safety and effectiveness data.

(b) For Tier 1 approval, the sponsor may be required to:

(i) submit and obtain approval for a registry protocol and/or an active surveillance plan

(ii) monitor for adverse events of special interest; and

(iii) submit periodic safety updates that will typically exceed in frequency those required for products approved for disease indications.

(c) For Tier 2 approval, the sponsor may be required to:

(i) develop and obtain approval of an active surveillance plan;

(ii) monitor for adverse events of special interest; and

(iii) submit periodic safety updates that may exceed those required for products approved for disease indications.

(4) **COEXISTING CLAIMS** —

(a) A dietary supplement healthspan claim is available only to the manufacturer or collaborating manufacturers.

(b) Awarding of the healthspan claim does not prevent marketing of similar products with structure-function claims.

(c) Manufacturers of similar products may not make the same or a substantially similar healthspan claim, refer to the claim, or imply the claim.

(d) Manufacturers of similar products without a healthspan claim may apply for the same or a higher-tier claim after the exclusivity of the issued claim has expired.

(5) **RELATIONSHIP TO EXISTING AUTHORITY**

(a) Nothing in this section shall be construed to:

(i) modify existing dietary supplement regulations except as specifically provided;

(ii) affect the authority of the Secretary under the Dietary Supplement Health and Education Act; or

(iii) create a premarket approval requirement for dietary supplements not making healthspan claims.

(G) TIER TRANSITION PROCEDURES

(1) **NO REQUIREMENT TO SEEK APPROVAL UNDER EACH TIER** — There shall be no requirement that a sponsor of a healthspan drug, dietary supplement, or device

establish safety and effectiveness under Tier 1 prior to seeking approval under Tiers 2 and 3, or under Tiers 1 and 2 prior to seeking approval under Tier 3.

(2) **APPLICATION FOR ADVANCEMENT** —

(a) Sponsors shall submit applications for tier advancement no later than 180 days before the expiration of the current tier period.

(b) The Secretary shall review and act upon such applications within 90 days.

(c) The Secretary in its discretion may extend the five-year term per tier and may extend the requirement for a sponsor to commence a clinical trial to generate data for higher tier approval by the second anniversary of a Tier 1 or Tier 2 approval, for up to two 180-day periods, provided the Secretary determines that the sponsor is making sufficient good-faith efforts to complete the conditions for maintaining or obtaining the applicable tier approval.

(3) **FAILURE TO ADVANCE** — Products failing to advance to higher tiers shall receive a 180-day period to submit additional data or analysis, as directed by the Secretary, to justify maintaining their current tier status pending review, and may be subject to labeling revisions as directed by the Secretary on or after the expiration of the 180-day period for submitting additional data or analysis.

(4) **REAPPLYING FOR TIER APPROVAL** — A sponsor may reapply at any time for any tier approval, if previously denied or if its healthspan product has been withdrawn from the market after failure to progress to a higher tier approval, provided that no similar or identical healthspan product is then being marketed with exclusivity under Tier 1, 2, or 3. Exclusivity for a product that regains approval in a given tier shall be limited to a cumulative exclusivity period of 5 years per tier.

(H) MARKET WITHDRAWAL AND ADMINISTRATIVE APPEALS — Products that fail to justify maintaining current tier status may, at the discretion of the Secretary, be subject to immediate withdrawal of approval of the product's healthspan indication, and market withdrawal as needed to protect public health, following notice and an opportunity to be heard under an abbreviated process as specified by the Secretary. The product's development or approval status for disease treatment indications, or, in the case of dietary supplements, for structure or function claims, will not be affected.

(1) **APPEAL RIGHTS** — Sponsors may appeal:

a. Denial of tier advancement

b. Withdrawal of tier designation

c. Labeling requirements

(2) **PROCEDURES** —

(a) Appeals must be filed within 60 days.

(b) The Secretary shall act within 90 days of the appeal.

(c) Products maintain status pending appeal.

SECTION 5. HEALTHSPAN PRODUCT DEVELOPMENT PROGRAM

(A) ESTABLISHMENT — The Secretary shall establish a program to expedite the development of healthspan products and facilitate ongoing communication between the Secretary and sponsors of healthspan products.

(B) HEALTHSPAN PRODUCT DEVELOPMENT MEETINGS —

(1) **TYPE H MEETINGS** — A sponsor of a healthspan product may request one or more meetings with the Secretary to:

(a) discuss the overall development program and goals for the product;

(b) obtain guidance on using novel endpoints and biomarkers;

(c) discuss study designs appropriate for demonstrating healthspan benefits;

(d) review proposed evidence generation plans;

(e) and obtain feedback on evidence collection strategies.

(2) **MEETING TYPES** —

(a) Type H1: Initial Healthspan Development Strategy Meeting

(b) Type H2: End of Phase 2 Meeting specific to healthspan endpoints

(c) Type H3: Pre-NDA/BLA Meeting for healthspan designation

(d) Type H4: Risk evaluation strategy meeting

(e) Type H5: Any other meeting needed to clarify specific product development points, including toxicology, safety, dosing, and product quality

(3) **MEETING TIMEFRAMES** — The Secretary shall meet with sponsors within:

(a) 75 calendar days of receipt of a Type H1 or H2 meeting request

(b) 60 calendar days of receipt of a Type H3 or H4 meeting request

(c) 45 calendar days of receipt of a Type H5 meeting request

(4) Meetings described in this subsection shall be in addition to, and not in place of, any other meetings or meeting types the applicant or sponsor may request under applicable regulations or guidance, provided that meetings not covered under this subsection may be denied as unnecessary if the same or essentially the same issues have been the subject of a Type H meeting or reasonably could have been the subject of a Type H meeting.

(C) CENTER FOR HEALTHSPAN PRODUCTS —

(1) ESTABLISHMENT — Not later than 90 days after the date of enactment of the THRIVE Act, the Secretary shall establish, within the Food and Drug Administration, the Center for Healthspan Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this chapter and related matters assigned by the Commissioner. The Center shall:

(a) include divisions and supervisory offices to conduct the review of healthspan products;

(b) provide specialized expertise in aging biology and biomarkers;

(c) develop guidance documents on healthspan product development;

(d) establish reporting requirements and systems for monitoring the safety of healthspan products and the effectiveness of healthspan products in reducing the risk of major chronic diseases; and

(e) facilitate coordination with external stakeholders.

(2) **GUIDANCE DOCUMENTS** — The Secretary shall issue guidance on:

(a) qualifying healthspan biomarkers

(b) novel clinical trial designs for healthspan products

(c) use of real-world evidence for healthspan products

(d) development considerations for healthspan drugs

(e) development considerations for healthspan devices

(f) development considerations for healthspan dietary supplements

(3) **ADVISORY COMMITTEE** —

(a) The Secretary shall establish within the Food and Drug Administration a Healthspan and Prevention Innovation Advisory Committee to:

(i) review applications,

(ii) evaluate biomarkers and outcomes,

(iii) develop detailed criteria for incentives, the award of prizes as authorized under this Act, and other recommendations to encourage innovation in the field of healthspan interventions and preventive medicine, nutrition, and wellness.

(D) HEALTHSPAN PRIORITY VOUCHER PROGRAM —

(1) **AWARD** — The Secretary shall award a priority review voucher to a sponsor for its:

(a) First Tier 3 approval for a healthspan drug or healthspan dietary supplement, in the case of a large company that:

(i) targets at least two major age-related chronic diseases, or

(ii) has received a Breakthrough Healthspan Drug Designation.

(b) First Tier 2 or Tier 3 approval for a healthspan drug or healthspan dietary supplement, in the case of an emerging company that

(i) targets at least two Major Age-Related Chronic Diseases, or

(ii) has received a Breakthrough Healthspan Drug Designation;

(c) First Tier 2 or Tier 3 approval for a healthspan drug that is a repurposed generic drug, i.e., a drug that has previously received approval for a non-healthspan indication and has become a generic drug (such a priority voucher for

a healthspan drug that is a repurposed generic could be in addition to the voucher mentioned in (a) or (b) above).

(d) Under exceptional circumstances to be defined by the Secretary, a priority voucher may be granted for a medical device Tier 3 clearance or approval.

(e) For purposes of this section, an "emerging company" is a company that meets all the following criteria:

(i) has never held an approved New Drug Application (NDA) or Biologics License Application (BLA) for any drug product;

(ii) has never, prior to the submission of a healthspan drug application, been the applicant for any drug product approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act; and

(iii) is not a subsidiary or affiliate of any entity that has held an approved NDA or BLA.

(f) For purposes of this section, a "large company" is any company that does not qualify as an emerging company under the above definition.

(2) **TRANSFERABILITY** — The voucher shall be transferable and may be used by the recipient to obtain priority review on any subsequent approval application or transfer it on mutually agreed terms to any third party, who can receive priority review for any product candidate of such third party.

(3) **LIMITATION** — No sponsor may be awarded more than one healthspan priority review voucher, except in the case of a sponsor who also successfully develops a Tier 2 or Tier 3 approval for a repurposed generic drug under section (d)(1)(c) above.

(4) **REDEMPTION** — The voucher entitles the holder to priority review of any single human drug application submitted under section 505(b)(1) or a biologics license application under section 351(a) or 351(k) of the Public Health Service Act.

(E) BREAKTHROUGH HEALTHSPAN PRODUCT DESIGNATION —

(1) **REQUEST FOR DESIGNATION:** Any sponsor of a healthspan drug, device, or dietary supplement may request the Secretary to designate a proposed product as a breakthrough healthspan product.

(2) **CRITERIA FOR DESIGNATION:** A product is eligible for designation as a breakthrough healthspan product if:

(a) It is intended to increase healthspan, defined as preventing or reversing two or more age-related chronic diseases and/or disabilities.

(b) Available scientific evidence indicates that the product has a high potential to make a major contribution to increasing healthspan either as an intervention, a surrogate endpoint, or a highly informative biomarker.

(3) **REVIEW AND DETERMINATION:** No later than 60 days after the receipt of a request under paragraph (1), the Secretary shall determine whether the product meets the criteria described in paragraph (2). If the Secretary determines that the product meets the criteria, the Secretary shall designate the product as a breakthrough healthspan product and take appropriate actions to expedite its development and review.

(4) **WRITTEN RATIONALE:** If the Secretary determines that a product does not meet the criteria for designation, the Secretary shall provide the sponsor with a written description of the rationale for such determination.

(5) **EXPEDITED DEVELOPMENT AND REVIEW:**

(a) A healthspan product designated under this section shall be eligible for priority review at each tier of healthspan approval, as appropriate, to facilitate its availability to the public.

(b) The sponsor of a healthspan product shall be eligible for early interactions with the Secretary to discuss potential healthspan biomarkers, surrogates, and endpoints that may be used to support the approval of the healthspan product at each tier.

(6) **DEFINITION; BREAKTHROUGH HEALTHSPAN PRODUCT:** For purposes of this section, the term "breakthrough healthspan product" includes any healthspan drug, device, or dietary supplement intended to improve healthspan and meet the criteria specified in this section.

SECTION 6. CLAIM EXCLUSIVITY AND ENFORCEMENT

(A) HEALTHSPAN CLAIM EXCLUSIVITY —

(1) **IN GENERAL** — Upon approval of a healthspan product, the holder of such approval shall have the exclusive right to make the approved healthspan claim(s) for the approved ingredient(s) or combination of ingredients, or, in the case of medical devices, those with the same or substantially similar purpose, mechanism and performance characteristics, for the duration of:

(a) 5 years for Tier 1 approved products;

(b) an additional 5 years upon achieving Tier 2 approval; and

(c) an additional 5 years upon achieving Tier 3 approval.

(2) **SCOPE OF EXCLUSIVITY** During the applicable exclusivity period:

(a) The Secretary shall not approve any additional product making the same or substantially similar healthspan claims for the same ingredient(s) or combination of ingredients, or, in the case of medical devices, those with the same or substantially similar purpose, mechanism, and performance characteristics.

(b) No entity or individual may make healthspan claims for products containing the same ingredient(s) or combination of ingredients without authorization from the exclusivity holder.

(c) On the date that is five years following the date of Tier 3 approval, no further exclusivity shall apply, and the sponsor of such Tier 3 healthspan product shall no longer have the exclusive right to make the approved healthspan claim or claims for the drug, device, or dietary supplement, as applicable, for the approved healthspan use.

(3) **DIETARY SUPPLEMENTS** —

(a) Exclusivity periods under this section shall apply to evidence-based healthspan claims for dietary supplements.

(b) Exclusivity shall be limited to the specific claim language and evidence presentation.

(c) Other manufacturers may make the same or similar claims if supported by independent evidence meeting the standards of Section 4(f).

(d) This Act neither modifies the Dietary Supplement Health and Education Act of 1994 (DSHEA) nor limits the marketing of dietary supplements as enabled by that law. The provisions herein create additional options and incentives for supplement manufacturers to seek healthspan claims.

(B) ENFORCEMENT OF EXCLUSIVITY —

(1) **IN GENERAL** — For products granted healthspan claim exclusivity under this section:

(a) The Secretary shall not grant approval of any additional product for the same healthspan indication during the exclusivity period.

(b) No entity or individual may make, use, prescribe, dispense, offer to sell, or sell any product making the same or substantially similar healthspan claims during the exclusivity period.

(2) **VIOLATION OF HEALTHSPAN CLAIM EXCLUSIVITY** —

(a) Any entity or individual that makes, uses, prescribes, dispenses, offers to sell, or sells a product with the same or substantially similar healthspan claims during the exclusivity period shall be deemed to have violated the healthspan claim exclusivity and shall be liable to the holder of such exclusivity.

(b) Whoever actively induces a violation of healthspan claim exclusivity shall be liable as a violator.

(C) PRIVATE RIGHT OF ACTION —

(1) **REMEDY FOR VIOLATION** — The holder of healthspan claim exclusivity under this section shall have a remedy by civil action for violation of such exclusivity.

(2) **INJUNCTIVE RELIEF** —

(a) The several courts having jurisdiction over cases under this section may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by healthspan claim exclusivity granted under this section, on such terms as the court deems reasonable.

(b) In cases of willful violation of healthspan claim exclusivity, the court may issue immediate temporary restraining orders and preliminary injunctions upon a showing of a substantial likelihood of success on the merits.

(3) **DAMAGES** —

(a) Upon finding for the claimant, the court shall award:

(i) damages adequate to compensate for the violation of exclusivity, but in no event less than a reasonable royalty for the unauthorized use;

(ii) interest and costs as fixed by the court;

(iii) attorney fees to the prevailing party in exceptional cases.

(b) When damages are not found by a jury, the court shall assess them.

(c) The court may increase damages up to three times the amount found or assessed in cases of willful violation.

(4) **STATUTE OF LIMITATIONS** —

(a) No recovery shall be had for any violation of healthspan claim exclusivity committed more than six years prior to filing the complaint.

(D) RELATIONSHIP TO OTHER EXCLUSIVITY PERIODS —

(1) Healthspan claim exclusivity under this section shall be:

(a) Independent of any other marketing exclusivity or patent term granted under this Act or other Federal law.

(b) In addition to any other applicable exclusivity periods.

(E) NOTICE REQUIREMENTS —

(1) The holder of healthspan claim exclusivity shall:

(a) Mark products with notice of exclusivity;

(b) Maintain a publicly accessible registry of protected claims;

(c) Provide notice to known competitors making unauthorized claims.

SECTION 7. RELATION TO STATE LAW FOR HEALTHSPAN PERODUCTS

(A) PREEMPTION —

(1) **IN GENERAL** — No State or political subdivision of a State may establish or continue in effect any requirement that:

(a) Relates to the regulation of healthspan products approved under this Act.

(b) Conflicts with requirements under this Act.

(c) Limits the availability of approved healthspan products.

(2) **PRESERVATION OF STATE AUTHORITY** — Nothing in this Act shall be construed to preempt:

(a) State product liability laws;

(b) State consumer protection laws; and

(c) State professional licensing requirements.

SECTION 8. HEALTHSPAN INNOVATION PRIZES

(A) ESTABLISHMENT — The Secretary shall establish the Healthspan Innovation Prize Program to incentivize the development of products that help reduce the risks, and/or slow the onset, of multiple age-related chronic diseases and/or disabilities, and some forms of cancer.

(B) PRIZE CATEGORIES —

(1) **BREAKTHROUGH PREVENTION/REJUVENATION PRIZE** —

(a) Up to five prizes of $100,000,000 each shall be awarded to sponsors who develop products that:

(i) demonstrate a substantial reduction in the risks, onset, and/or severity of, or substantial reversal in, two or more Major Age-Related Chronic Diseases in a defined pre-disease population.

(ii) are cost-effective compared to standard interventions.

SECTION 9. PREVENTIVE MEDICINE EXCLUSIVITY ENHANCEMENTS

(A) ENHANCED EXCLUSIVITY —

(1) **PREVENTION IMPACT EXCLUSIVITY** —

(a) The Secretary shall award an additional 3 years of healthspan claim exclusivity to products that demonstrate:

(i) significant prevention of disease onset in high-risk populations,

(ii) reduction in healthcare utilization and costs, and/or

(iii) improvement in quality-of-life metrics.

(2) **POPULATION HEALTH EXCLUSIVITY** —

(a) The Secretary shall award an additional 2 years of healthspan claim exclusivity to products that achieve:

(i) documented improvement in population health outcomes;

(ii) reduction in health disparities; or

(iii) cost savings to the healthcare system.

SECTION 10. COLLABORATION BETWEEN FDA AND CENTERS FOR MEDICARE & MEDICAID SERVICES TO SUPPORT DEVELOPMENT AND APPROVAL OF HEALTHSPAN PRODUCTS

(A) INTERAGENCY FRAMEWORK — The Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) shall establish and maintain an interagency framework for collaboration to accelerate and support the development, approval, and coverage of healthspan products, including drugs, devices, and dietary supplements.

(B) PARALLEL REVIEW PROGRAM — FDA and CMS shall establish a parallel review program allowing simultaneous evaluation of clinical evidence for healthspan products, with the goal of expediting the regulatory approval and coverage determination process. Product sponsors may elect to participate in the parallel review to obtain timely input from both agencies on trial designs and evidentiary standards.

(C) INFORMATION SHARING — FDA and CMS shall regularly exchange information relevant to the review and coverage of healthspan products, including (but not limited to):

(1) Key advances in regulatory science relevant to the evaluation of healthspan products,

(2) Lists of upcoming healthspan product submissions and advisory committee meetings,

(3) Data on post-market performance, safety, and real-world effectiveness,

(4) And best practices for evaluating healthspan indications.

(D) JOINT GUIDANCE AND STAKEHOLDER ENGAGEMENT — FDA and CMS shall issue joint guidance, when appropriate, on standards for clinical evidence required for both regulatory approval and coverage decisions for healthspan products. Both agencies shall engage collaboratively with stakeholders, including sponsors and patient groups, to support product development.

(E) COORDINATED POSTMARKET MONITORING — FDA and CMS shall establish mechanisms for coordinated post-market monitoring of healthspan products, sharing real-world evidence related to utilization, outcomes, safety, and effectiveness in defined populations.

(F) JOINT TRAINING INITIATIVES — Both agencies shall participate in joint training and educational programs to ensure staff maintain a full understanding of healthspan concepts, regulatory criteria, and payer requirements.

(G) REPORTING AND EVALUATION — FDA and CMS shall jointly report annually to Congress on the outcomes, efficiency, and impact of their collaborative efforts related to developing, approving, and covering healthspan products. The report shall include data on review timelines, product access, and health outcomes in covered populations.