and for which the existence of such investigations has been made public, unless—

"(1) such drug or such biological product was marketed in food before any approval of the drug under section 505, before licensure of the biological product under such section 351, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

"(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

"(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

"(A) a regulation issued under section 409 prescribing conditions of safe use in food;

"(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

"(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

"(D) a food contact substance notification that is effective under section 409(h); or

"(E) such drug or biological product had been marketed for smoking cessation prior to the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

"(4) the drug is a new animal drug whose use is not unsafe under section 512.".

(b) CONFORMING CHANGES.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

21 USC 334. (1) in section 304(a)(1), by striking "section 404 or 505" and inserting "section 301(ll), 404, or 505"; and

21 USC 381. (2) in section 801(a), by striking "is adulterated, misbranded, or in violation of section 505," and inserting "is adulterated, misbranded, or in violation of section 505, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll),".

SEC. 913. ASSURING PHARMACEUTICAL SAFETY.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as amended in section 403, is amended by inserting after section 505C the following:

21 USC 355e. **"SEC. 505D. PHARMACEUTICAL SECURITY.**

Standards. "(a) IN GENERAL.—The Secretary shall develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs.

"(b) STANDARDS DEVELOPMENT.—

"(1) IN GENERAL.—The Secretary shall, in consultation with the agencies specified in paragraph (4), manufacturers, distributors, pharmacies, and other supply chain stakeholders, prioritize and develop standards for the identification, validation, authentication, and tracking and tracing of prescription drugs.

"(2) STANDARDIZED NUMERAL IDENTIFIER.—Not later than 30 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall develop a standardized numerical identifier (which, to the extent practicable, shall be harmonized with international consensus standards for such an identifier) to be applied to a prescription drug at the point of manufacturing and repackaging (in which case the numerical identifier shall be linked to the numerical identifier applied at the point of manufacturing) at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug. Deadline.

"(3) PROMISING TECHNOLOGIES.—The standards developed under this subsection shall address promising technologies, which may include—

"(A) radio frequency identification technology;

"(B) nanotechnology;

"(C) encryption technologies; and

"(D) other track-and-trace or authentication technologies.

"(4) INTERAGENCY COLLABORATION.—In carrying out this subsection, the Secretary shall consult with Federal health and security agencies, including—

"(A) the Department of Justice;

"(B) the Department of Homeland Security;

"(C) the Department of Commerce; and

"(D) other appropriate Federal and State agencies.

"(c) INSPECTION AND ENFORCEMENT.—

"(1) IN GENERAL.—The Secretary shall expand and enhance the resources and facilities of agency components of the Food and Drug Administration involved with regulatory and criminal enforcement of this Act to secure the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs including biological products and active pharmaceutical ingredients from domestic and foreign sources.

"(2) ACTIVITIES.—The Secretary shall undertake enhanced and joint enforcement activities with other Federal and State agencies, and establish regional capacities for the validation of prescription drugs and the inspection of the prescription drug supply chain.

"(d) DEFINITION.—In this section, the term 'prescription drug' means a drug subject to section 503(b)(1).".

SEC. 914. CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 901(a), is amended by adding at the end the following:

"(q) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—