By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Purpose*. Americans spend more per capita on pharmaceutical drugs than residents of any other developed country. Americans often pay more for the exact same drugs, even when they are produced and shipped from the exact same facilities.

One way to minimize international disparities in price is to increase the trade of prescription drugs between nations with lower prices and those with persistently higher ones. Over time, reducing trade barriers and increasing the exchange of drugs will likely result in lower prices for the country that is paying more for drugs. For example, in the European Union, a market characterized by price controls and significant barriers to entry, the parallel trade of drugs has existed for decades and has been estimated to reduce the price of certain drugs by up to 20 percent. Accordingly, my Administration supports the goal of safe importation of prescription drugs.

SEC. 2. *Permitting the Importation of Safe Prescription Drugs from Other Countries*. The Secretary of Health and Human Services shall, as appropriate and consistent with applicable law, take action to expand safe access to lower-cost imported prescription drugs by:

(a) facilitating grants to individuals of waivers of the prohibition of importation of prescription drugs, provided such importation poses no additional risk to public safety and results in lower costs to American patients, pursuant to section 804(j)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 384(j)(2);

(b) authorizing the re-importation of insulin products upon a finding by the Secretary that it is required for emergency medical care pursuant to section 801(d) of the FDCA, 21 U.S.C. 381(d); and

(c) completing the rulemaking process regarding the proposed rule to implement section 804(b) through (h) of the FDCA, 21 U.S.C. 384(b) through (h), to allow importation of certain prescription drugs from Canada.

SEC. 3. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

§ 384a. Foreign supplier verification program

(a) In general

(1) Verification requirement

Except as provided under subsections (e) and (f), each importer shall perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer or agent of an importer is—

(A) produced in compliance with the requirements of section 350g of this title or section 350h of this title, as appropriate; and

(B) is not adulterated under section 342 of this title or misbranded under section 343(w) of this title.

(2) Importer defined

For purposes of this section, the term ''importer'' means, with respect to an article of food—

(A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or

(B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.

(b) Guidance

Not later than 1 year after January 4, 2011, the Secretary shall issue guidance to assist importers in developing foreign supplier verification programs.

(c) Regulations

(1) In general

Not later than 1 year after January 4, 2011, the Secretary shall promulgate regulations to provide for the content of the foreign supplier verification program established under subsection (a).

(2) Requirements

The regulations promulgated under paragraph (1)—

(A) shall require that the foreign supplier verification program of each importer be adequate to provide assurances that each foreign supplier to the importer produces the imported food in compliance with—

(i) processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under section 350g of this title or section 350h of this title (taking into consideration variances granted under section 350h of this title), as appropriate; and

(ii) section 342 of this title and section 343(w) of this title.[1]

(B) shall include such other requirements as the Secretary deems necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States.

(3) Considerations

In promulgating regulations under this subsection, the Secretary shall, as appropriate, take into account differences among importers and types of imported foods, including based on the level of risk posed by the imported food.

(4) Activities

Verification activities under a foreign supplier verification program under this section may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments.

(d) Record maintenance and access

Records of an importer related to a foreign supplier verification program shall be maintained for a period of not less than 2 years and

[1] So in original.

shall be made available promptly to a duly authorized representative of the Secretary upon request.

(e) Exemption of seafood, juice, and low-acid canned food facilities in compliance with HACCP

This section shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with, 1 of the following standards and regulations with respect to such facility:

(1) The Seafood Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

(2) The Juice Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

(3) The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the Food and Drug Administration (or any successor standards).

The exemption under paragraph (3) shall apply only with respect to microbiological hazards that are regulated under the standards for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers under part 113 of chapter[2] 21, Code of Federal Regulations (or any successor regulations).

(f) Additional exemptions

The Secretary, by notice published in the Federal Register, shall establish an exemption from the requirements of this section for articles of food imported in small quantities for research and evaluation purposes or for personal consumption, provided that such foods are not intended for retail sale and are not sold or distributed to the public.

(g) Publication of list of participants

The Secretary shall publish and maintain on the Internet Web site of the Food and Drug Administration a current list that includes the name of, location of, and other information deemed necessary by the Secretary about, importers participating under this section.

(June 25, 1938, ch. 675, § 805, as added Pub. L. 111–353, title III, § 301(a), Jan. 4, 2011, 124 Stat. 3953.)

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective 2 years after Jan. 4, 2011, see section 301(d) of Pub. L. 111–353, set out as an Effective Date of 2011 Amendment note under section 331 of this title.

CONSTRUCTION

Nothing in this section to be construed to apply to certain alcohol-related facilities, to alter jurisdiction and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

§ 384b. Voluntary qualified importer program

(a) In general

Beginning not later than 18 months after January 4, 2011, the Secretary shall—

(1) establish a program, in consultation with the Secretary of Homeland Security—

(A) to provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such program; and

(B) consistent with section 384d of this title, establish a process for the issuance of a facility certification to accompany food offered for importation by importers who have voluntarily agreed to participate in such program; and

(2) issue a guidance document related to participation in, revocation of such participation in, reinstatement in, and compliance with, such program.

(b) Voluntary participation

An importer may request the Secretary to provide for the expedited review and importation of designated foods in accordance with the program established by the Secretary under subsection (a).

(c) Notice of intent to participate

An importer that intends to participate in the program under this section in a fiscal year shall submit a notice and application to the Secretary of such intent at the time and in a manner established by the Secretary.

(d) Eligibility

Eligibility shall be limited to an importer offering food for importation from a facility that has a certification described in subsection (a). In reviewing the applications and making determinations on such applications, the Secretary shall consider the risk of the food to be imported based on factors, such as the following:

(1) The known safety risks of the food to be imported.

(2) The compliance history of foreign suppliers used by the importer, as appropriate.

(3) The capability of the regulatory system of the country of export to ensure compliance with United States food safety standards for a designated food.

(4) The compliance of the importer with the requirements of section 384a of this title.

(5) The recordkeeping, testing, inspections and audits of facilities, traceability of articles of food, temperature controls, and sourcing practices of the importer.

(6) The potential risk for intentional adulteration of the food.

(7) Any other factor that the Secretary determines appropriate.

(e) Review and revocation

Any importer qualified by the Secretary in accordance with the eligibility criteria set forth in this section shall be reevaluated not less often than once every 3 years and the Secretary shall promptly revoke the qualified importer status of any importer found not to be in compliance with such criteria.

(f) False statements

Any statement or representation made by an importer to the Secretary shall be subject to section 1001 of title 18.

(g) Definition

For purposes of this section, the term ''importer'' means the person that brings food, or

[2] So in original. Probably should be ''title''.