

“(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.

“(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.—

“(1) IN GENERAL.—

“(A) DETERMINATION.—The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) because of any request to take any form of action relating to the application, either before or during consideration of the request, unless—

“(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

“(ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.

“(B) NOTIFICATION.—If the Secretary determines under subparagraph (A) that a delay is necessary with respect to an application, the Secretary shall provide to the applicant, not later than 30 days after making such determination, the following information:

“(i) Notification of the fact that a determination under subparagraph (A) has been made.

“(ii) If applicable, any clarification or additional data that the applicant should submit to the docket on the petition to allow the Secretary to review the petition promptly.

“(iii) A brief summary of the specific substantive issues raised in the petition which form the basis of the determination.

“(C) FORMAT.—The information described in subparagraph (B) shall be conveyed via either, at the discretion of the Secretary—

“(i) a document; or

“(ii) a meeting with the applicant involved.

“(D) PUBLIC DISCLOSURE.—Any information conveyed by the Secretary under subparagraph (C) shall be considered part of the application and shall be subject to the disclosure requirements applicable to information in such application.

“(E) DENIAL BASED ON INTENT TO DELAY.—If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination. The Secretary may issue guidance to describe the factors that will be used to determine under this subparagraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

“(F) FINAL AGENCY ACTION.—The Secretary shall take final agency action on a petition not later than 180 days after the date on which the petition is submitted. The Secretary shall not extend such period for any reason, including—

“(i) any determination made under subparagraph (A);

“(ii) the submission of comments relating to the petition or supplemental information supplied by the petitioner; or

“(iii) the consent of the petitioner.

“(G) EXTENSION OF 30-MONTH PERIOD.—If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a petition, the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

“(H) CERTIFICATION.—The Secretary shall not consider a petition for review unless the party submitting such petition does so in written form and the subject document is signed and contains the following certification: ‘I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.’, with the date on which such information first became known to such party and the names of such persons or organizations inserted in the first and second blank space, respectively.

“(I) VERIFICATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and the subject document is signed and contains the following verification: ‘I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.’, with the date on which such information first became known

to the party and the names of such persons or organizations inserted in the first and second blank space, respectively.

“(2) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

“(A) FINAL AGENCY ACTION WITHIN 180 DAYS.—The Secretary shall be considered to have taken final agency action on a petition if—

“(i) during the 180-day period referred to in paragraph (1)(F), the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

“(ii) such period expires without the Secretary having made such a final decision.

“(B) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed against the Secretary with respect to any issue raised in the petition before the Secretary has taken final agency action on the petition within the meaning of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

“(C) ADMINISTRATIVE RECORD.—For purposes of judicial review related to the approval of an application for which a petition under paragraph (1) was submitted, the administrative record regarding any issue raised by the petition shall include—

“(i) the petition filed under paragraph (1) and any supplements and comments thereto;

“(ii) the Secretary’s response to such petition, if issued; and

“(iii) other information, as designated by the Secretary, related to the Secretary’s determinations regarding the issues raised in such petition, as long as the information was considered by the agency no later than the date of final agency action as defined under subparagraph (2)(A), and regardless of whether the Secretary responded to the petition at or before the approval of the application at issue in the petition.

“(3) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—

“(A) the number of applications that were approved during the preceding 12-month period;

“(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period;

“(C) the number of days by which such applications were so delayed; and

“(D) the number of such petitions that were submitted during such period.

“(4) EXCEPTIONS.—This subsection does not apply to—

“(A) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

“(B) a petition that is made by the sponsor of an application and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

“(5) DEFINITIONS.—

“(A) APPLICATION.—For purposes of this subsection, the term ‘application’ means an application submitted under subsection (b)(2) or (j).

“(B) PETITION.—For purposes of this subsection, other than paragraph (1)(A)(i), the term ‘petition’ means a request described in paragraph (1)(A)(i).”

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Congress on ways to encourage the early submission of petitions under section 505(q), as added by subsection (a).

SEC. 915. POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 914(a), is amended by adding at the end the following:

“(r) POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.—

“(1) ESTABLISHMENT.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall improve the transparency of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site that—

“(A) provides links to drug safety information listed in paragraph (2) for prescription drugs that are approved under this section or licensed under section 351 of the Public Health Service Act; and

“(B) improves communication of drug safety information to patients and providers.

“(2) INTERNET WEB SITE.—The Secretary shall carry out paragraph (1) by—

“(A) developing and maintaining an accessible, consolidated Internet Web site with easily searchable drug safety information, including the information found on United States Government Internet Web sites, such as the United States National Library of Medicine’s Daily Med and Medline Plus Web sites, in addition to other such Web sites maintained by the Secretary;

“(B) ensuring that the information provided on the Internet Web site is comprehensive and includes, when available and appropriate—

“(i) patient labeling and patient packaging inserts;

“(ii) a link to a list of each drug, whether approved under this section or licensed under such section 351, for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

“(iii) a link to the registry and results data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act;

“(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;