

fiscal year limitation. Such fees shall be collected in each fiscal year in an amount equal to the amount specified in appropriations Acts for such fiscal year and shall only be collected and available for the costs of the Food and Drug Administration.

(C) For purposes of this paragraph, a certification by the Secretary shall be made on such basis, and in such form (including a publicly available listing) as the Secretary determines appropriate.

(D) With regard to fees pursuant to subparagraph (B) in connection with written export certifications for food:

(i) Such fees shall be collected and available solely for the costs of the Food and Drug Administration associated with issuing such certifications.

(ii) Such fees may not be retained in an amount that exceeds such costs for the respective fiscal year.

(f) Labeling of exported drugs

(1) If a drug (other than insulin, an antibiotic drug, an animal drug, or a drug exported under section 382 of this title) being exported in accordance with subsection (e) of this section is being exported to a country that has different or additional labeling requirements or conditions for use and such country requires the drug to be labeled in accordance with those requirements or uses, such drug may be labeled in accordance with such requirements and conditions for use in the country to which such drug is being exported if it also is labeled in accordance with the requirements of this chapter.

(2) If, pursuant to paragraph (1), the labeling of an exported drug includes conditions for use that have not been approved under this chapter, the labeling must state that such conditions for use have not been approved under this chapter. A drug exported under section 382 of this title is exempt from this section.

(g) Warning notice of importation in violation of chapter

(1) With respect to a prescription drug being imported or offered for import into the United States, the Secretary, in the case of an individual who is not in the business of such importations, may not send a warning notice to the individual unless the following conditions are met:

(A) The notice specifies, as applicable to the importation of the drug, that the Secretary has made a determination that—

(i) importation is in violation of subsection (a) of this section because the drug is or appears to be adulterated, misbranded, or in violation of section 355 of this title;

(ii) importation is in violation of subsection (a) of this section because the drug is or appears to be forbidden or restricted in sale in the country in which it was produced or from which it was exported;

(iii) importation is or appears to be in violation of subsection (d)(1) of this section; or

(iv) importation otherwise is or appears to be in violation of Federal law.

(B) The notice does not specify any provision described in subparagraph (A) that is not applicable to the importation of the drug.

(C) The notice states the reasons underlying such determination by the Secretary, including a brief application to the principal facts involved of the provision of law described in subparagraph (A) that is the basis of the determination by the Secretary.

(2) For purposes of this section, the term “warning notice”, with respect to the importation of a drug, means a communication from the Secretary (written or otherwise) notifying a person, or clearly suggesting to the person, that importing the drug for personal use is, or appears to be, a violation of this chapter.

(h) Protection against adulteration of food

(1) The Secretary shall give high priority to increasing the number of inspections under this section for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food.

(2) The Secretary shall give high priority to making necessary improvements to the information management systems of the Food and Drug Administration that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with this chapter.

(3) The Secretary shall improve linkages with other regulatory agencies of the Federal Government that share responsibility for food safety, and shall with respect to such safety improve linkages with the States and Indian tribes (as defined in section 450b(e) of title 25).

(i) Testing for rapid detection of adulteration of food

(1) For use in inspections of food under this section, the Secretary shall provide for research on the development of tests and sampling methodologies—

(A) whose purpose is to test food in order to rapidly detect the adulteration of the food, with the greatest priority given to detect the intentional adulteration of food; and

(B) whose results offer significant improvements over the available technology in terms of accuracy, timing, or costs.

(2) In providing for research under paragraph (1), the Secretary shall give priority to conducting research on the development of tests that are suitable for inspections of food at ports of entry into the United States.

(3) In providing for research under paragraph (1), the Secretary shall as appropriate coordinate with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Administrator of the Environmental Protection Agency, and the Secretary of Agriculture.

(4) The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the progress made in research under paragraph (1), including progress regarding paragraph (2).