(b) TECHNICAL AMENDMENTS.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

(1) by striking ''(f) AWARENESS EFFORTS'' and inserting ''(e) AWARENESS EFFORTS''; and

(2) by striking ''(e) CONSTRUCTION'' and inserting ''(f) CONSTRUCTION''.

Subtitle C—FDA Advancement of Precision Medicine

SEC. 2041. PRECISION MEDICINE GUIDANCE AND OTHER PROGRAMS OF FOOD AND DRUG ADMINISTRATION.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''Subchapter J—Precision Medicine

''SEC. 591. GENERAL AGENCY GUIDANCE ON PRECISION MEDICINE.

''(a) IN GENERAL.—The Secretary shall issue and periodically update guidance to assist sponsors in the development of a precision drug or biological product. Such guidance shall—

''(1) define the term 'precision drug or biological product'; and

''(2) address the topics described in subsection (b).

''(b) CERTAIN ISSUES.—The topics to be addressed by guidance under subsection (a) are—

''(1) the evidence needed to support the use of biomarkers (as defined in section 507(e)) that identify subsets of patients as likely responders to therapies in order to streamline the conduct of clinical trials;

''(2) recommendations for the design of studies to demonstrate the validity of a biomarker as a predictor of drug or biological product response;

''(3) the manner and extent to which a benefit-risk assessment may be affected when clinical trials are limited to patient population subsets that are identified using biomarkers;

''(4) the development of companion diagnostics in the context of a drug development program; and

''(5) considerations for developing biomarkers that inform prescribing decisions for a drug or biological product, and when information regarding a biomarker may be included in the approved prescription labeling for a precision drug or biological product.

''(c) DATE CERTAIN FOR INITIAL GUIDANCE.—The Secretary shall issue guidance under subsection (a) not later than 18 months after the date of the enactment of the 21st Century Cures Act.

"SEC. 592. PRECISION MEDICINE REGARDING ORPHAN-DRUG AND EXPEDITED-APPROVAL PROGRAMS.

''(a) IN GENERAL.—In the case of a precision drug or biological product that is the subject of an application submitted under section 505(b)(1), or section 351(a) of the Public Health Service Act, for the treatment of a serious or life-threatening disease or condition and has been designated under section 526 as a drug for a rare disease or condition, the Secretary may—

''(1) consistent with applicable standards for approval, rely upon data or information previously submitted by the sponsor of the precision drug or biological product, or another sponsor, provided that the sponsor of the precision drug or biological product has obtained a contractual right of reference to such other sponsor's data and information, in an application approved under section 505(c) or licensed under section 351(a) of the Public Health Service Act, as applicable—

''(A) for a different drug or biological product; or

''(B) for a different indication for such precision drug or biological product,

in order to expedite clinical development for a precision drug or biological product that is using the same or similar approach as that used to support approval of the prior approved application or license, as appropriate; and

''(2) as appropriate, consider the application for approval of such precision drug or biological product to be eligible for expedited review and approval programs described in section 506, including accelerated approval in accordance with subsection (c) of such section.

''(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

''(1) limit the authority of the Secretary to approve products pursuant to this Act and the Public Health Service Act as authorized prior to the date of enactment of this section; or

''(2) confer any new rights, beyond those authorized under this Act prior to enactment of this section, with respect to a sponsor's ability to reference information contained in another application

submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act.''.

Subtitle D—Modern Trial Design and Evidence Development

SEC. 2061. BROADER APPLICATION OF BAYESIAN STATISTICS AND ADAPTIVE TRIAL DESIGNS.

(a) PROPOSALS FOR USE OF INNOVATIVE STATISTICAL METHODS IN CLINICAL PROTOCOLS FOR DRUGS AND BIOLOGICAL PRODUCTS.—For purposes of assisting sponsors in incorporating adaptive trial design and Bayesian methods into proposed clinical protocols and applications for new drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and biological products under section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary shall conduct a public meeting and issue guidance in accordance with subsection (b).

(b) GUIDANCE ADDRESSING USE OF ADAPTIVE TRIAL DESIGNS AND BAYESIAN METHODS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs (in this subsection referred to as the ''Secretary''), shall—