sessment (as such terms are defined in subsection (f) of such section 507).

SEC. 2022. ACCELERATED APPROVAL DEVELOPMENT PLAN.

(a) IN GENERAL.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended by adding the following subsection:

"(g) ACCELERATED APPROVAL DEVELOPMENT PLAN.—

"(1) IN GENERAL.—In the case of a drug that the Secretary determines may be eligible for accelerated approval in accordance with subsection (c), the sponsor of such drug may request, at any time after the submission of an application for the investigation of the drug under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act, that the Secretary agree to an accelerated approval development plan described in paragraph (2).

"(2) PLAN DESCRIBED.—A plan described in this paragraph, with respect to a drug described in paragraph (1), is an accelerated approval development plan, which shall include agreement on—

"(A) the surrogate endpoint to be assessed under such plan;

"(B) the design of the study that will utilize the surrogate endpoint; and

"(C) the magnitude of the effect of the drug on the surrogate endpoint that is the subject of the agreement that would be sufficient to form the primary basis of a claim that the drug is effective.

"(3) MODIFICATION; TERMINATION.—The Secretary may require the sponsor of a drug that is the subject of an accelerated approval development plan to modify or terminate the plan if additional data or information indicates that—

"(A) the plan as originally agreed upon is no longer sufficient to demonstrate the safety and effectiveness of the drug involved; or

"(B) the drug is no longer eligible for accelerated approval under subsection (c).

"(4) SPONSOR CONSULTATION.—If the Secretary requires the modification or termination of an accelerated approval development plan under paragraph (3), the sponsor shall be granted a request for a meeting to discuss the basis of the Secretary's decision before the effective date of the modification or termination.

"(5) DEFINITION.—In this section, the term 'accelerated approval development plan' means a development plan agreed upon by the Secretary and

the sponsor submitting the plan that contains study parameters for the use of a surrogate endpoint that—

"(A) is reasonably likely to predict clinical benefit; and

"(B) is intended to be the basis of the accelerated approval of a drug in accordance with subsection (c).".

(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: