and Human Services shall convene a public meeting to solicit input on the guidance.

Subtitle B—Qualification and Use of Drug Development Tools

SEC. 2021. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

(a) FINDINGS.—Congress finds the following:

(1) Development of new drugs has become increasingly challenging and resource intensive.

(2) Development of drug development tools can benefit the availability of new medical therapies by helping to translate scientific discoveries into clinical applications.

(3) Biomedical research consortia (as defined in section 507(f) of section 507 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c)) can play a valuable role in helping develop and qualify drug development tools.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) Congress should promote and facilitate a collaborative effort among the biomedical research consortia described in subsection (a)(3)—

(A) to develop, through a transparent public process, data standards and scientific ap-

proaches to data collection accepted by the medical and clinical research community for purposes of qualifying drug development tools;

(B) to coordinate efforts toward developing and qualifying drug development tools in key therapeutic areas; and

(C) to encourage the development of accessible databases for collecting relevant drug development tool data for such purposes; and

(2) an entity seeking to qualify a drug development tool should be encouraged, in addition to consultation with the Secretary, to consult with biomedical research consortia and other individuals and entities with expert knowledge and insights that may assist the requestor and benefit the process for such qualification.

(c) QUALIFICATION OF DRUG DEVELOPMENT TOOLS.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 506F the following new section:

"SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

''(a) PROCESS FOR QUALIFICATION.—

''(1) IN GENERAL.—The Secretary shall establish a process for the qualification of drug develop-

ment tools for a proposed context of use under which—

''(A)(i) a requestor initiates such process by submitting a letter of intent to the Secretary; and

''(ii) the Secretary shall accept or decline to accept such letter of intent;

''(B)(i) if the Secretary accepts the letter of intent, a requestor shall submit a qualification plan to the Secretary; and

''(ii) the Secretary shall accept or decline to accept the qualification plan; and

''(C)(i) if the Secretary accepts the qualification plan, the requestor submits to the Secretary a full qualification package;

''(ii) the Secretary shall determine whether to accept such qualification package for review; and

''(iii) if the Secretary accepts such qualification package for review, conduct such review in accordance with this section.

''(2) ACCEPTANCE AND REVIEW OF SUBMISSIONS.—

''(A) IN GENERAL.—The succeeding provisions of this paragraph shall apply with respect

to the treatment of a letter of intent, a qualification plan, or a full qualification package submitted under paragraph (1) (referred to in this paragraph as 'qualification submissions').

''(B) ACCEPTANCE FACTORS; NON-ACCEPTANCE.—The Secretary shall determine whether to accept a qualification submission based on factors which may include the scientific merit of the submission and the available resources of the Food and Drug Administration to review the qualification submission. A determination not to accept a submission under paragraph (1) shall not be construed as a final determination by the Secretary under this section regarding the qualification of a drug development tool for its proposed context of use.

''(C) PRIORITIZATION OF QUALIFICATION REVIEW.—The Secretary may prioritize the review of a full qualification package submitted under paragraph (1) with respect to a drug development tool, based on factors determined appropriate by the Secretary, including—

''(i) as applicable, the severity, rarity, or prevalence of the disease or condition targeted by the drug development tool and

the availability or lack of alternative treatments for such disease or condition; and

''(ii) the identification, by the Secretary or by biomedical research consortia and other expert stakeholders, of such a drug development tool and its proposed context of use as a public health priority.

''(D) ENGAGEMENT OF EXTERNAL EXPERTS.—The Secretary may, for purposes of the review of qualification submissions, through the use of cooperative agreements, grants, or other appropriate mechanisms, consult with biomedical research consortia and may consider the recommendations of such consortia with respect to the review of any qualification plan submitted under paragraph (1) or the review of any full qualification package under paragraph (3).

''(3) REVIEW OF FULL QUALIFICATION PACKAGE.—The Secretary shall—

''(A) conduct a comprehensive review of a full qualification package accepted under paragraph (1)(C); and

''(B) determine whether the drug development tool at issue is qualified for its proposed context of use.

''(4) QUALIFICATION.—The Secretary shall determine whether a drug development tool is qualified for a proposed context of use based on the scientific merit of a full qualification package reviewed under paragraph (3).

''(b) EFFECT OF QUALIFICATION.—

''(1) IN GENERAL.—A drug development tool determined to be qualified under subsection (a)(4) for a proposed context of use specified by the requestor may be used by any person in such context of use for the purposes described in paragraph (2).

''(2) USE OF A DRUG DEVELOPMENT TOOL.—Subject to paragraph (3), a drug development tool qualified under this section may be used for—

''(A) supporting or obtaining approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act; or

''(B) supporting the investigational use of a drug or biological product under section

505(i) of this Act or section 351(a)(3) of the Public Health Service Act.

''(3) RESCISSION OR MODIFICATION.—

''(A) IN GENERAL.—The Secretary may rescind or modify a determination under this section to qualify a drug development tool if the Secretary determines that the drug development tool is not appropriate for the proposed context of use specified by the requestor. Such a determination may be based on new information that calls into question the basis for such qualification.

''(B) MEETING FOR REVIEW.—If the Secretary rescinds or modifies under subparagraph (A) a determination to qualify a drug development tool, the requestor involved shall be granted a request for a meeting with the Secretary to discuss the basis of the Secretary's decision to rescind or modify the determination before the effective date of the rescission or modification.

''(c) TRANSPARENCY.—

''(1) IN GENERAL.—Subject to paragraph (3), the Secretary shall make publicly available, and update on at least a biannual basis, on the Internet

website of the Food and Drug Administration the following:

''(A) Information with respect to each qualification submission under the qualification process under subsection (a), including—

''(i) the stage of the review process applicable to the submission;

''(ii) the date of the most recent change in stage status;

''(iii) whether the external scientific experts were utilized in the development of a qualification plan or the review of a full qualification package; and

''(iv) submissions from requestors under the qualification process under subsection (a), including any data and evidence contained in such submissions, and any updates to such submissions.

''(B) The Secretary's formal written determinations in response to such qualification submissions.

''(C) Any rescissions or modifications under subsection (b)(3) of a determination to qualify a drug development tool.

''(D) Summary reviews that document conclusions and recommendations for determinations to qualify drug development tools under subsection (a).

''(E) A comprehensive list of—

''(i) all drug development tools qualified under subsection (a); and

''(ii) all surrogate endpoints which were the basis of approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act.

''(2) RELATION TO TRADE SECRETS ACT.—Information made publicly available by the Secretary under paragraph (1) shall be considered a disclosure authorized by law for purposes of section 1905 of title 18, United States Code.

''(3) APPLICABILITY.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information contained in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act that is confidential commercial or trade secret information sub-

ject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

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

''(1) to alter the standards of evidence under subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d), or under section 351 of the Public Health Service Act (as applicable); or

''(2) to limit the authority of the Secretary to approve or license products under to this Act or the Public Health Service Act, as applicable (as in effect before the date of the enactment of the 21st Century Cures Act).

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $10,000,000 for each of fiscal years 2016 through 2020.

''(f) DEFINITIONS.—In this section:

''(1) BIOMARKER.—(A) The term 'biomarker' means a characteristic (such as a physiologic, pathologic, or anatomic characteristic or measurement) that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic

processes, or biological responses to a therapeutic intervention; and

''(B) such term includes a surrogate endpoint.

''(2) BIOMEDICAL RESEARCH CONSORTIA.—The term 'biomedical research consortia' means collaborative groups that may take the form of public-private partnerships and may include government agencies, institutions of higher education (as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001)), patient advocacy groups, industry representatives, clinical and scientific experts, and other relevant entities and individuals.

''(3) CLINICAL OUTCOME ASSESSMENT.—(A) The term 'clinical outcome assessment' means a measurement of a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions; and

''(B) such term includes a patient-reported outcome.

''(4) CONTEXT OF USE.—The term 'context of use' means, with respect to a drug development tool, a statement that describes the circumstances under which the drug development tool is to be used in drug development and regulatory review.

''(5) DRUG DEVELOPMENT TOOL.—The term 'drug development tool' includes—

''(A) a biomarker;

''(B) a clinical outcome assessment; and

''(C) any other method, material, or measure that the Secretary determines aids drug development and regulatory review for purposes of this section.

''(6) PATIENT-REPORTED OUTCOME.—The term 'patient-reported outcome' means a measurement based on a report from a patient regarding the status of the patient's health condition without amendment or interpretation of the patient's report by a clinician or any other person.

''(7) QUALIFICATION.—The terms 'qualification' and 'qualified' mean a determination by the Secretary that a drug development tool and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review under this Act.

''(8) REQUESTOR.—The term 'requestor' means an entity or entities, including a drug sponsor or a biomedical research consortia, seeking to qualify a drug development tool for a proposed context of use under this section.

''(9) SURROGATE ENDPOINT.—The term 'surrogate endpoint' means a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure, that is not itself a direct measurement of clinical benefit, and—

''(A) is known to predict clinical benefit and could be used to support traditional approval of a drug or biological product; or

''(B) is reasonably likely to predict clinical benefit and could be used to support the accelerated approval of a drug or biological product in accordance with section 506(c).''.

(d) GUIDANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall, in consultation with biomedical research consortia (as defined in subsection (f) of section 507 the Federal Food, Drug, and Cosmetic Act (as added by subsection (c))) and other interested parties through a collaborative public process, issue guidance to implement such section 507 that—

(A) provides a conceptual framework describing appropriate standards and scientific approaches to support the development of bio-

markers delineated under the taxonomy established under paragraph (3);

(B) makes recommendations for demonstrating that a surrogate endpoint is reasonably likely to predict clinical benefit for the purpose of supporting the accelerated approval of a drug under section 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c));

(C) with respect to the qualification process under such section 507—

(i) describes the requirements that entities seeking to qualify a drug development tool under such section shall observe when engaging in such process;

(ii) outlines reasonable timeframes for the Secretary's review of letters, qualification plans, or full qualification packages submitted under such process; and

(iii) establishes a process by which such entities or the Secretary may consult with biomedical research consortia and other individuals and entities with expert knowledge and insights that may assist the Secretary in the review of qualification

plans and full qualification submissions under such section; and

(D) includes such other information as the Secretary determines appropriate.

(2) TIMING.—Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue draft guidance under paragraph (1) on the implementation of section 507 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (c)). The Secretary shall issue final guidance on the implementation of such section not later than 6 months after the date on which the comment period for the draft guidance closes.

(3) TAXONOMY.—

(A) IN GENERAL.—For purposes of informing guidance under this subsection, the Secretary shall, in consultation with biomedical research consortia and other interested parties through a collaborative public process, establish a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug development.

(B) PUBLIC AVAILABILITY.—Not later than 12 months after the date of the enactment of this Act, the Secretary shall make such tax-

onomy publicly available in draft form for public comment. The Secretary shall finalize the taxonomy not later than 12 months after the close of the public comment period.

(e) MEETING AND REPORT.—

(1) MEETING.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall convene a public meeting to describe and solicit public input regarding the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c).

(2) REPORT.—Not later than 5 years after the date of the enactment of this Act, the Secretary shall make publicly available on the Internet website of the Food and Drug Administration a report. Such report shall include, with respect to the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c), information on—

(A) the number of requests submitted, as a letter of intent, for qualification of a drug development tool (as defined in subsection (f) of such section);

(B) the number of such requests accepted and determined to be eligible for submission of a qualification plan or full qualification package (as such terms are defined in such subsection), respectively;

(C) the number of such requests for which external scientific experts were utilized in the development of a qualification plan or review of a full qualification package; and

(D) the number of qualification plans and full qualification packages, respectively, submitted to the Secretary; and

(3) the drug development tools qualified through such qualification process, specified by type of tool, such as a biomarker or clinical outcome assessment (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 acceler-