tion 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

Subtitle G—Antibiotic Drug Development

SEC. 2121. APPROVAL OF CERTAIN DRUGS FOR USE IN A LIMITED POPULATION OF PATIENTS.

(a) PURPOSE.—The purpose of this section is to help expedite the development and availability of treatments for serious or life-threatening bacterial or fungal infections in patients with unmet needs, while maintaining safety and effectiveness standards for such treatments, taking into account the severity of the infection and the availability or lack of alternative treatments.

(b) APPROVAL OF CERTAIN ANTIBACTERIAL AND ANTIFUNGAL DRUGS.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 2001, is further amended by adding at the end the following new subsection:

"(z) APPROVAL OF CERTAIN ANTIBACTERIAL AND ANTIFUNGAL DRUGS FOR USE IN A LIMITED POPULATION OF PATIENTS.—

"(1) PROCESS.—At the request of the sponsor of an antibacterial or antifungal drug that is intended to treat a serious or life-threatening infection, the Secretary—

"(A) may execute a written agreement with the sponsor on the process for developing data to support an application for approval of such drug, for use in a limited population of patients in accordance with this subsection;

"(B) shall proceed with the development and approval of such a drug in accordance with this subsection only if a written agreement is reached under subparagraph (A);

"(C) shall provide the sponsor with an opportunity to request meetings under paragraph (2);

"(D) if a written agreement is reached under subparagraph (A), may approve the drug under this subsection for such use —

"(i) in a limited population of patients for which there is an unmet medical need;

"(ii) based on a streamlined development program; and

"(iii) only if the standards for approval under subsections (c) and (d) of this section or licensure under section 351 of the Public Health Service Act, as applicable, are met; and

''(E) in approving a drug in accordance with this subsection, subject to subparagraph (D)(iii), may rely upon—

''(i) traditional endpoints, alternate endpoints, or a combination of traditional and alternate endpoints, and, as appropriate, data sets of a limited size; and

''(ii)(I) additional data, including preclinical, pharmacologic, or pathophysiologic evidence;

''(II) nonclinical susceptibility and pharmacokinetic data;

''(III) data from phase 2 clinical trials; and

''(IV) such other confirmatory evidence as the Secretary determines appropriate to approve the drug.

''(2) FORMAL MEETINGS.—

''(A) IN GENERAL.—To help expedite and facilitate the development and review of a drug for which a sponsor intends to request approval in accordance with this subsection, the Secretary may, at the request of the sponsor, conduct meetings that provide early consultation, timely advice, and sufficient opportunities to

develop an agreement described in paragraph (1)(A) and help the sponsor design and conduct a drug development program as efficiently as possible, including the following types of meetings:

''(i) An early consultation meeting.

''(ii) An assessment meeting.

''(iii) A postapproval meeting.

''(B) NO ALTERING OF GOALS.—Nothing in this paragraph shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

''(C) BREAKTHROUGH THERAPIES.—In the case of a drug designated as a breakthrough therapy under section 506(a), the sponsor of such drug may elect to utilize meetings provided under such section with respect to such drug in lieu of meetings described in subparagraph (A).

''(3) LABELING REQUIREMENT.—The labeling of an antibacterial or antifungal drug approved in accordance with this subsection shall contain the statement 'Limited Population' in a prominent man-

ner and adjacent to, and not more prominent than, the brand name of the product. The prescribing information for such antibacterial or antifungal drug required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) shall also include the following statement: 'This drug is indicated for use in a limited and specific population of patients.'.

''(4) PROMOTIONAL MATERIALS.—The provisions of section 506(c)(2)(B) shall apply with respect to approval in accordance with this subsection to the same extent and in the same manner as such provisions apply with respect to accelerated approval in accordance with section 506(c)(1).

''(5) TERMINATION OF REQUIREMENTS OR CONDITIONS.—If a drug is approved in accordance with this subsection for an indication in a limited population of patients and is subsequently approved or licensed under this section or section 351 of the Public Health Service Act, other than in accordance with this subsection, for—

''(A) the same indication and the same conditions of use, the Secretary shall remove any labeling requirements or postmarketing

conditions that were made applicable to the drug under this subsection; or

"(B) a different indication or condition of use, the Secretary shall not apply the labeling requirements and postmarketing conditions that were made applicable to the drug under this subsection to the subsequent approval of the drug for such different indication or condition of use.

"(6) RELATION TO OTHER PROVISIONS.—Nothing in this subsection shall be construed to prohibit the approval of a drug for use in a limited population of patients in accordance with this subsection, in combination with—

"(A) an agreement on the design and size of a clinical trial pursuant to subparagraphs (B) and (C) of subsection (b)(5);

"(B) designation and treatment of the drug as a breakthrough therapy under section 506(a);

"(C) designation and treatment of the drug as a fast track product under section 506(b); or

"(D) accelerated approval of the drug in accordance with section 506(c).

''(7) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed—

''(A) to alter the standards of evidence under subsection (c) or (d) (including the substantial evidence standard in subsection (d));

''(B) to waive or otherwise preclude the application of requirements under subsection (o);

''(C) to otherwise, in any way, 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 subsection; or

''(D) to restrict in any manner, the prescribing of antibiotics or other products by health care providers, or to otherwise limit or restrict the practice of health care.

''(8) EFFECTIVE IMMEDIATELY.—The Secretary shall have the authorities vested in the Secretary by this subsection beginning on the date of enactment of this subsection, irrespective of when and whether the Secretary promulgates final regulations or guidance.

''(9) DEFINITIONS.—In this subsection:

''(A) EARLY CONSULTATION MEETING.—The term 'early consultation meeting' means a

pre-investigational new drug meeting or an end-of-phase 1 meeting that—

"(i) is conducted to review and reach a written agreement—

"(I) on the scope of the streamlined development plan for a drug for which a sponsor intends to request approval in accordance with this subsection; and

"(II) which, as appropriate, may include agreement on the design and size of necessary preclinical and clinical studies early in the development process, including clinical trials whose data are intended to form the primary basis for an effectiveness claim; and

"(ii) provides an opportunity to discuss expectations of the Secretary regarding studies or other information that the Secretary deems appropriate for purposes of applying paragraph (5), relating to the termination of labeling requirements or postmarketing conditions.

"(B) ASSESSMENT MEETING.—The term 'assessment meeting' means an end-of-phase 2

meeting, pre-new drug application meeting, or pre-biologics license application meeting conducted to resolve questions and issues raised during the course of clinical investigations, and details addressed in the written agreement regarding postapproval commitments or expansion of approved uses.

''(C) POSTAPPROVAL MEETING.—The term 'postapproval meeting' means a meeting following initial approval or licensure of the drug for use in a limited population, to discuss any issues identified by the Secretary or the sponsor regarding postapproval commitments or expansion of approved uses.''.

(c) GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance describing criteria, process, and other general considerations for demonstrating the safety and effectiveness of antibacterial and antifungal drugs to be approved for use in a limited population in accordance with section 505(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b).

(d) CONFORMING AMENDMENTS.—

(1) LICENSURE OF CERTAIN BIOLOGICAL PRODUCTS.—Section 351(j) of the Public Health Service Act (42 U.S.C. 262(j)) is amended—

(A) by striking ''(j)'' and inserting ''(j)(1)'';

(B) by inserting ''505(z),'' after ''505(p),''; and

(C) by adding at the end the following new paragraph:

''(2) In applying section 505(z) of the Federal Food, Drug, and Cosmetic Act to the licensure of biological products under this section—

''(A) references to an antibacterial or antifungal drug that is intended to treat a serious or life-threatening infection shall be construed to refer to a biological product intended to treat a serious or life-threatening bacterial or fungal infection; and

''(B) references to approval of a drug under section 505(c) of such Act shall be construed to refer to a licensure of a biological product under subsection (a) of this section.''.

(2) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following new subsection:

''(dd) If it is a drug approved in accordance with section 505(z) and its labeling does not meet the requirements under paragraph (3) of such subsection, subject to paragraph (5) of such subsection.''.

(e) EVALUATION.—

(1) ASSESSMENT.—Not later than 48 months after the date of enactment of this Act, the Secretary of Health and Human Services shall publish for public comment an assessment of the program established under section 505(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b). Such assessment shall determine if the limited-use pathway established under such section 505(z) has improved or is likely to improve patient access to novel antibacterial or antifungal treatments and assess how the pathway could be expanded to cover products for serious or life-threatening diseases or conditions beyond bacterial and fungal infections.

(2) MEETING.—Not later than 90 days after the date of the publication of such assessment, the Secretary, acting through the Commissioner of Food and Drugs shall hold a public meeting to discuss the findings of the assessment, during which public stakeholders may present their views on the success

of the program established under section 505(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), and the appropriateness of expanding such program.

(f) EXPANSION OF PROGRAM.—If the Secretary of Health and Human Services determines, based on the assessment under subsection (e)(1), evaluation of the assessment, and any other relevant information, that the public health would benefit from expansion of the limited-use pathway established under section 505(z) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (b)) beyond the drugs approved in accordance with such section, the Secretary may expand such limited-use pathway in accordance with such a determination. The approval of any drugs under any such expansion shall be subject to the considerations and requirements described in such section 505(z) for purposes of expansion to other serious or life-threatening diseases or conditions.

(g) MONITORING.—The Public Health Service Act is amended by inserting after section 317T (42 U.S.C. 247b–22) the following:

"SEC. 317U. MONITORING ANTIBACTERIAL AND ANTIFUNGAL DRUG USE AND RESISTANCE.

''(a) MONITORING.—The Secretary shall use an appropriate monitoring system to monitor—

''(1) the use of antibacterial and antifungal drugs, including those receiving approval or licensure for a limited population pursuant to section 505(z) of the Federal Food, Drug, and Cosmetic Act; and

''(2) changes in bacterial and fungal resistance to drugs.

''(b) PUBLIC AVAILABILITY OF DATA.—The Secretary shall make summaries of the data derived from monitoring under this section publicly available for the purposes of—

''(1) improving the monitoring of important trends in antibacterial and antifungal resistance; and

''(2) ensuring appropriate stewardship of antibacterial and antifungal drugs, including those receiving approval or licensure for a limited population pursuant to section 505(z) of the Federal Food, Drug, and Cosmetic Act.''.

SEC. 2122. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS.

(a) IN GENERAL.—Section 511 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a) is amended to read as follows: