sistent with the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act (as amended by this title), the Secretary shall consider the application under the applicable requirements of section 512 (as so amended).''

GUIDANCE ADDRESSING INVESTIGATION DESIGNS

Pub. L. 115–234, title III, § 305, Aug. 14, 2018, 132 Stat. 2440, provided that:

''(a) IN GENERAL.—For purposes of assisting sponsors in incorporating complex adaptive and other novel investigation designs, data from foreign countries, real world evidence (including ongoing surveillance activities, observational studies, and registry data), biomarkers, and surrogate endpoints (referred to in this section as 'elements of investigations') into proposed clinical investigation protocols and applications for new animal drugs under sections 512 and 571 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b; 360ccc), the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall issue guidance addressing the use of such elements of investigations in the development and regulatory review of such new animal drugs.

''(b) CONTENTS.—The guidance under subsection (a) shall address how the Secretary will evaluate the elements of investigations proposed or submitted pursuant to section 512(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act or to meet the commitment under section 571(a)(2)(F) of such Act, and how sponsors of such applications may obtain feedback from the Secretary on technical issues related to such investigations prior to the submission of an application to the Secretary.

''(c) MEETING.—Prior to issuing the guidance under subsection (a), the Secretary shall consult with stakeholders, including representatives of regulated industry, consumer groups, academia, veterinarians, and food producers, through a public meeting to be held not later than 1 year after the date of enactment of this Act [Aug. 14, 2018].

''(d) TIMING.—The Secretary shall issue a draft guidance under subsection (a) not later than 1 year after the date of the public meeting under subsection (c), and shall finalize such guidance not later than 1 year after the date on which the public comment period on such draft guidance ends.''

ANTIMICROBIAL ANIMAL DRUG DISTRIBUTION REPORTS

Pub. L. 110–316, title I, § 105(b), (c), Aug. 14, 2008, 122 Stat. 3514, provided that:

''(b) FIRST REPORT.—For each new animal drug that is subject to the reporting requirement under section 512(*l*)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b(*l*)(3)], as added by subsection (a), and for which an approval of an application filed pursuant to section 512(b) or 571 of such Act [21 U.S.C. 360b(b), 360ccc] is in effect on the date of the enactment of this title [Aug. 14, 2008], the Secretary of Health and Human Services shall require the sponsor of the drug to submit the first report under such section 512(*l*)(3) for the drug not later than March 31, 2010.

''(c) SEPARATE REPORT.—The reports required under section 512(*l*)(3) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall be separate from periodic drug experience reports that are required under section 514.80(b)(4) of title 21, Code of Federal Regulations (as in effect on the date of the enactment of this title).''

DRUGS INTENDED FOR MINOR SPECIES AND MINOR USES

Pub. L. 104–250, § 2(f), Oct. 9, 1996, 110 Stat. 3154, provided that: ''The Secretary of Health and Human Services shall consider legislative and regulatory options for facilitating the approval under section 512 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b] of animal drugs intended for minor species and for minor uses and, within 18 months after the date of enactment of this Act [Oct. 9, 1996], announce proposals for legislative or regulatory change to the approval process under such section for animal drugs intended for use in minor species or for minor uses.''

TRANSITIONAL PROVISION REGARDING IMPLEMENTATION OF PUB. L. 104–250; APPROVED MEDICATED FEED APPLICATION DEEMED LICENSE

Pub. L. 104–250, § 6(c), Oct. 9, 1996, 110 Stat. 3160, provided that: ''A person engaged in the manufacture of animal feeds bearing or containing new animal drugs who holds at least one approved medicated feed application for an animal feed bearing or containing new animal drugs, the manufacture of which was not otherwise exempt from the requirement for an approved medicated feed application on the date of the enactment of this Act [Oct. 9, 1996], shall be deemed to hold a license for the manufacturing site identified in the approved medicated feed application. The revocation of license provisions of section 512(m)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b(m)(4)], as amended by this Act, shall apply to such licenses. Such license shall expire within 18 months from the date of enactment of this Act unless the person submits to the Secretary a completed license application for the manufacturing site accompanied by a copy of an approved medicated feed application for such site, which license application shall be deemed to be approved upon receipt by the Secretary.''

DRUGS PRIMARILY MANUFACTURED USING BIOTECHNOLOGY

Pub. L. 100–670, title I, § 106, Nov. 16, 1988, 102 Stat. 3984, provided that: ''Notwithstanding section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b(b)(2)], the Secretary of Health and Human Services may not approve an abbreviated application submitted under such section for a new animal drug which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques.''

§ 360b–1. Priority zoonotic animal drugs

(a) In general

The Secretary shall, at the request of the sponsor intending to submit an application for approval of a new animal drug under section 360b(b)(1) of this title or an application for conditional approval of a new animal drug under section 360ccc of this title, expedite the development and review of such new animal drug if preliminary clinical evidence indicates that the new animal drug, alone or in combination with 1 or more other animal drugs, has the potential to prevent or treat a zoonotic disease in animals, including a vector borne-disease, that has the potential to cause serious adverse health consequences for, or serious or life-threatening diseases in, humans.

(b) Request for designation

The sponsor of a new animal drug may request the Secretary to designate a new animal drug described in subsection (a) as a priority zoonotic animal drug. A request for the designation may be made concurrently with, or at any time after, the opening of an investigational new animal drug file under section 360b(j) of this title or the filing of an application under section 360b(b)(1) or 360ccc of this title.

(c) Designation

(1) In general

Not later than 60 calendar days after the receipt of a request under subsection (b), the

Secretary shall determine whether the new animal drug that is the subject of the request meets the criteria described in subsection (a). If the Secretary determines that the new animal drug meets the criteria, the Secretary shall designate the new animal drug as a priority zoonotic animal drug and shall take such actions as are appropriate to expedite the development and review of the application for approval or conditional approval of such new animal drug.

(2) Actions

The actions to expedite the development and review of an application under paragraph (1) may include, as appropriate—

(A) taking steps to ensure that the design of clinical trials is as efficient as practicable, when scientifically appropriate, such as by utilizing novel trial designs or drug development tools (including biomarkers) that may reduce the number of animals needed for studies;

(B) providing timely advice to, and interactive communication with, the sponsor (which may include meetings with the sponsor and review team) regarding the development of the new animal drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable;

(C) involving senior managers and review staff with experience in zoonotic or vector-borne disease to facilitate collaborative, cross-disciplinary review, including, as appropriate, across agency centers; and

(D) implementing additional administrative or process enhancements, as necessary, to facilitate an efficient review and development program.

(June 25, 1938, ch. 675, § 512A, as added Pub. L. 116–136, div. A, title III, § 3302, Mar. 27, 2020, 134 Stat. 384.)

§ 360c. Classification of devices intended for human use

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.—

(i) A device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) CLASS II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) CLASS III, PREMARKET APPROVAL.—A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 360d and 360e of this title, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

(3)(A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 360d and 360e of this