

the medical product development process and consider the perspectives of patients during regulatory discussions, including by—

(1) fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with medical product sponsors and investigators; and

(2) exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.

**(b) Protection of proprietary information**

Nothing in this section shall be construed to alter the protections offered by laws, regulations, or policies governing disclosure of confidential commercial or trade secret information and any other information exempt from disclosure pursuant to section 552(b) of title 5 as such laws, regulations, or policies would apply to consultation with individuals and organizations prior to July 9, 2012.

**(c) Other consultation**

Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to July 9, 2012.

**(d) No right or obligation**

Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder. Nothing in this section 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. Nothing in this section is intended to increase the number of review cycles as in effect before July 9, 2012.

**(e) Financial interest**

In this section, the term “financial interest” means a financial interest under section 208(a) of title 18.

(June 25, 1938, ch. 675, § 569C, as added Pub. L. 112-144, title XI, § 1137, July 9, 2012, 126 Stat. 1124.)

REFERENCES IN TEXT

Section 101(b) of the Prescription Drug User Fee Amendments of 2012, referred to in subsec. (d), is section 101(b) of Pub. L. 112-144, which is set out as a note under section 379g of this title.

PART F—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

**§ 360ccc. Conditional approval of new animal drugs for minor use and minor species**

**(a) Application requirements; contents; restrictions**

(1) Except as provided in paragraph (3) of this section,<sup>1</sup> any person may file with the Secretary an application for conditional approval of a new animal drug intended for a minor use or a minor species. Such an application may not be a supplement to an application approved under sec-

tion 360b of this title. Such application must comply in all respects with the provisions of section 360b of this title except sections 360b(a)(4), 360b(b)(2), 360b(c)(1), 360b(c)(2), 360b(c)(3), 360b(d)(1), 360b(e), 360b(h), and 360b(n) of this title unless otherwise stated in this section, and any additional provisions of this section. New animal drugs are subject to application of the same safety standards that would be applied to such drugs under section 360b(d) of this title (including, for antimicrobial new animal drugs, with respect to antimicrobial resistance).

(2) The applicant shall submit to the Secretary as part of an application for the conditional approval of a new animal drug—

(A) all information necessary to meet the requirements of section 360b(b)(1) of this title except section 360b(b)(1)(A) of this title;

(B) full reports of investigations which have been made to show whether or not such drug is safe under section 360b(d) of this title (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance) and there is a reasonable expectation of effectiveness for use;

(C) data for establishing a conditional dose;

(D) projections of expected need and the justification for that expectation based on the best information available;

(E) information regarding the quantity of drug expected to be distributed on an annual basis to meet the expected need; and

(F) a commitment that the applicant will conduct additional investigations to meet the requirements for the full demonstration of effectiveness under section 360b(d)(1)(E) of this title within 5 years.

(3) A person may not file an application under paragraph (1) if—

(A) the application seeks conditional approval of a new animal drug that is contained in, or is a product of, a transgenic animal.<sup>2</sup>

(B) the person has previously filed an application for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not subsequently conditionally approved by the Secretary under subsection (b) of this section, or

(C) the person obtained the application, or data or other information contained therein, directly or indirectly from the person who filed for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not subsequently conditionally approved by the Secretary under subsection (b) of this section.

**(b) Order of approval or hearing**

Within 180 days after the filing of an application pursuant to subsection (a) of this section, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(1) issue an order, effective for one year, conditionally approving the application if the Secretary finds that none of the grounds for denying conditional approval, specified in subsection (c) of this section applies and publish

<sup>1</sup> So in original. Probably should be “this subsection.”

<sup>2</sup> So in original. The period probably should be a comma.

a Federal Register notice of the conditional approval, or

(2) give the applicant notice of an opportunity for an informal hearing on the question whether such application can be conditionally approved.

**(c) Order of approval or refusal after hearing**

If the Secretary finds, after giving the applicant notice and an opportunity for an informal hearing, that—

(1) any of the provisions of section 360b(d)(1)(A) through (D) or (F) through (I) of this title are applicable;

(2) the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such drug, is insufficient to show that there is a reasonable expectation that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or

(3) another person has received approval under section 360b of this title for the same drug in the same dosage form for the same intended use, and that person is able to assure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended;

the Secretary shall issue an order refusing to conditionally approve the application. If, after such notice and opportunity for an informal hearing, the Secretary finds that paragraphs (1) through (3) do not apply, the Secretary shall issue an order conditionally approving the application effective for one year and publish a Federal Register notice of the conditional approval. Any order issued under this subsection refusing to conditionally approve an application shall state the findings upon which it is based.

**(d) Effective period; renewal; refusal of renewal**

A conditional approval under this section is effective for a 1-year period and is thereafter renewable by the Secretary annually for up to 4 additional 1-year terms. A conditional approval shall be in effect for no more than 5 years from the date of approval under subsection (b)(1) or (c) of this section unless extended as provided for in subsection (h) of this section. The following shall also apply:

(1) No later than 90 days from the end of the 1-year period for which the original or renewed conditional approval is effective, the applicant may submit a request to renew a conditional approval for an additional 1-year term.

(2) A conditional approval shall be deemed renewed at the end of the 1-year period, or at the end of a 90-day extension that the Secretary may, at the Secretary's discretion, grant by letter in order to complete review of the renewal request, unless the Secretary determines before the expiration of the 1-year period or the 90-day extension that—

(A) the applicant failed to submit a timely renewal request;

(B) the request fails to contain sufficient information to show that—

(i) the applicant is making sufficient progress toward meeting approval require-

ments under section 360b(d)(1)(E) of this title, and is likely to be able to fulfill those requirements and obtain an approval under section 360b of this title before the expiration of the 5-year maximum term of the conditional approval;

(ii) the quantity of the drug that has been distributed is consistent with the conditionally approved intended use and conditions of use, unless there is adequate explanation that ensures that the drug is only used for its intended purpose; or

(iii) the same drug in the same dosage form for the same intended use has not received approval under section 360b of this title, or if such a drug has been approved, that the holder of the approved application is unable to assure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended; or

(C) any of the provisions of section 360b(e)(1)(A) through (B) or (D) through (F) of this title are applicable.

(3) If the Secretary determines before the end of the 1-year period or the 90-day extension, if granted, that a conditional approval should not be renewed, the Secretary shall issue an order refusing to renew the conditional approval, and such conditional approval shall be deemed withdrawn and no longer in effect. The Secretary shall thereafter provide an opportunity for an informal hearing to the applicant on the issue whether the conditional approval shall be reinstated.

(4)(A) In the case of an application under subsection (a) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act [21 U.S.C. 801 et seq.], conditional approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act [21 U.S.C. 811(j)].

(B) For purposes of this section, with respect to an application described in subparagraph (A), the term "date of approval" shall mean the later of—

(i) the date an application under subsection (a) is conditionally approved under subsection (b); or

(ii) the date of issuance of the interim final rule controlling the drug.

**(e) Withdrawal of conditional approval**

(1) The Secretary shall issue an order withdrawing conditional approval of an application filed pursuant to subsection (a) of this section if the Secretary finds that another person has received approval under section 360b of this title for the same drug in the same dosage form for the same intended use and that person is able to assure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended.

(2) The Secretary shall, after due notice and opportunity for an informal hearing to the applicant, issue an order withdrawing conditional approval of an application filed pursuant to sub-

section (a) of this section if the Secretary finds that—

(A) any of the provisions of section 360b(e)(1)(A) through (B) or (D) through (F) of this title are applicable; or

(B) on the basis of new information before the Secretary with respect to such drug, evaluated together with the evidence available to the Secretary when the application was conditionally approved, that there is not a reasonable expectation that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

(3) The Secretary may also, after due notice and opportunity for an informal hearing to the applicant, issue an order withdrawing conditional approval of an application filed pursuant to subsection (a) of this section if the Secretary finds that any of the provisions of section 360b(e)(2) of this title are applicable.

**(f) Labeling**

(1) The label and labeling of a new animal drug with a conditional approval under this section shall—

(A) bear the statement, “conditionally approved by FDA pending a full demonstration of effectiveness under application number”; and

(B) contain such other information as prescribed by the Secretary.

(2) An intended use that is the subject of a conditional approval under this section shall not be included in the same product label with any intended use approved under section 360b of this title.

**(g) Amendment of application**

A conditionally approved new animal drug application may not be amended or supplemented to add indications for use.

**(h) Order of approval after conditional approval period termination**

180 days prior to the termination date established under subsection (d) of this section, an applicant shall have submitted all the information necessary to support a complete new animal drug application in accordance with section 360b(b)(1) of this title or the conditional approval issued under this section is no longer in effect. Following review of this information, the Secretary shall either—

(1) issue an order approving the application under section 360b(c) of this title if the Secretary finds that none of the grounds for denying approval specified in section 360b(d)(1) of this title applies, or

(2) give the applicant an opportunity for a hearing before the Secretary under section 360b(d) of this title on the question whether such application can be approved.

Upon issuance of an order approving the application, product labeling and administrative records of approval shall be modified accordingly. If the Secretary has not issued an order under section 360b(c) of this title approving such application prior to the termination date established under subsection (d) of this section, the

conditional approval issued under this section is no longer in effect unless the Secretary grants an extension of an additional 180-day period so that the Secretary can complete review of the application. The decision to grant an extension is committed to the discretion of the Secretary and not subject to judicial review.

**(i) Judicial review**

The decision of the Secretary under subsection (c), (d), or (e) of this section refusing or withdrawing conditional approval of an application shall constitute final agency action subject to judicial review.

**(j) Definition**

In this section and section 360ccc-1 of this title, the term “transgenic animal” means an animal whose genome contains a nucleotide sequence that has been intentionally modified in vitro, and the progeny of such an animal; Provided that the term “transgenic animal” does not include an animal of which the nucleotide sequence of the genome has been modified solely by selective breeding.

(June 25, 1938, ch. 675, §571, as added Pub. L. 108-282, title I, §102(b)(4), Aug. 2, 2004, 118 Stat. 892; amended Pub. L. 114-89, §2(a)(3)(B), Nov. 25, 2015, 129 Stat. 699.)

REFERENCES IN TEXT

The Controlled Substances Act, referred to in subsec. (d)(4)(A), is title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, which is classified principally to subchapter I (§801 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

AMENDMENTS

2015—Subsec. (d)(4). Pub. L. 114-89 added par. (4).

FINDINGS

Pub. L. 108-282, title I, §102(a), Aug. 2, 2004, 118 Stat. 891, provided that: “Congress makes the following findings:

“(1) There is a severe shortage of approved new animal drugs for use in minor species.

“(2) There is a severe shortage of approved new animal drugs for treating animal diseases and conditions that occur infrequently or in limited geographic areas.

“(3) Because of the small market shares, low-profit margins involved, and capital investment required, it is generally not economically feasible for new animal drug applicants to pursue approvals for these species, diseases, and conditions.

“(4) Because the populations for which such new animal drugs are intended may be small and conditions of animal management may vary widely, it is often difficult to design and conduct studies to establish drug safety and effectiveness under traditional new animal drug approval processes.

“(5) It is in the public interest and in the interest of animal welfare to provide for special procedures to allow the lawful use and marketing of certain new animal drugs for minor species and minor uses that take into account these special circumstances and that ensure that such drugs do not endanger animal or public health.

“(6) Exclusive marketing rights for clinical testing expenses have helped encourage the development of ‘orphan’ drugs for human use, and comparable incentives should encourage the development of new animal drugs for minor species and minor uses.”

REGULATIONS

Pub. L. 108-282, title I, §102(b)(6), Aug. 2, 2004, 118 Stat. 905, provided that: “On the date of enactment of

this Act [Aug. 2, 2004], the Secretary of Health and Human Services shall implement sections 571 and 573 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360ccc, 360ccc-2] and subsequently publish implementing regulations. Not later than 12 months after the date of enactment of this Act, the Secretary shall issue proposed regulations to implement section 573 of the Federal Food, Drug, and Cosmetic Act (as added by this Act), and not later than 24 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing section 573 of the Federal Food, Drug, and Cosmetic Act. Not later than 18 months after the date of enactment of this Act, the Secretary shall issue proposed regulations to implement section 572 of the Federal Food, Drug, and Cosmetic Act (as added by this Act) [21 U.S.C. 360ccc-1], and not later than 36 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing section 572 of the Federal Food, Drug, and Cosmetic Act. Not later than 30 months after the date of enactment of this Act, the Secretary shall issue proposed regulations to implement section 571 of the Federal Food, Drug, and Cosmetic Act (as added by this Act), and not later than 42 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing section 571 of the Federal Food, Drug, and Cosmetic Act. These timeframes shall be extended by 12 months for each fiscal year, in which the funds authorized to be appropriated under subsection (i) [no subsection (i) of section 102 has been enacted] are not in fact appropriated.”

**§ 360ccc-1. Index of legally marketed unapproved new animal drugs for minor species**

**(a) Establishment and content**

(1) The Secretary shall establish an index limited to—

(A) new animal drugs intended for use in a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals; and

(B) new animal drugs intended for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, non-food life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with the standard of section 360b(d) of this title (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance).

(2) The index shall not include a new animal drug that is contained in or a product of a transgenic animal.

**(b) Conferences**

Any person intending to file a request under this section shall be entitled to one or more conferences to discuss the requirements for indexing a new animal drug.

**(c) Request for determination of eligibility for inclusion in index**

(1) Any person may submit a request to the Secretary for a determination whether a new animal drug may be eligible for inclusion in the index. Such a request shall include—

(A) information regarding the need for the new animal drug, the species for which the new animal drug is intended, the proposed intended use and conditions of use, and anticipated annual distribution;

(B) information to support the conclusion that the proposed use meets the conditions of

subparagraph (A) or (B) of subsection (a)(1) of this section;

(C) information regarding the components and composition of the new animal drug;

(D) a description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such new animal drug;

(E) an environmental assessment that meets the requirements of the National Environmental Policy Act of 1969 [42 U.S.C. 4321 et seq.], as amended, and as defined in 21 CFR Part 25, as it appears on August 2, 2004, and amended thereafter or information to support a categorical exclusion from the requirement to prepare an environmental assessment;

(F) information sufficient to support the conclusion that the proposed use of the new animal drug is safe under section 360b(d) of this title with respect to individuals exposed to the new animal drug through its manufacture or use; and

(G) such other information as the Secretary may deem necessary to make this eligibility determination.

(2) Within 90 days after the submission of a request for a determination of eligibility for indexing based on subsection (a)(1)(A) of this section, or 180 days for a request submitted based on subsection (a)(1)(B) of this section, the Secretary shall grant or deny the request, and notify the person who requested such determination of the Secretary's decision. The Secretary shall grant the request if the Secretary finds that—

(A) the same drug in the same dosage form for the same intended use is not approved or conditionally approved;

(B) the proposed use of the drug meets the conditions of subparagraph (A) or (B) of subsection (a)(1) of this section, as appropriate;

(C) the person requesting the determination has established appropriate specifications for the manufacture and control of the new animal drug and has demonstrated an understanding of the requirements of current good manufacturing practices;

(D) the new animal drug will not significantly affect the human environment; and

(E) the new animal drug is safe with respect to individuals exposed to the new animal drug through its manufacture or use.

If the Secretary denies the request, the Secretary shall thereafter provide due notice and an opportunity for an informal conference. A decision of the Secretary to deny an eligibility request following an informal conference shall constitute final agency action subject to judicial review.

**(d) Request for addition to index**

(1) With respect to a new animal drug for which the Secretary has made a determination of eligibility under subsection (c) of this section, the person who made such a request may ask that the Secretary add the new animal drug to the index established under subsection (a) of this section. The request for addition to the index shall include—

(A) a copy of the Secretary's determination of eligibility issued under subsection (c) of this section;