necessary for the administration of section 512 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b], as amended by sections 101 through 103 of this title, within one year of the date of enactment of this Act [Nov. 16, 1988].

“(b) Transition.—During the period beginning 60 days after the date of enactment of this Act [Nov. 16, 1988] and ending on the date regulations promulgated under subsection (a) take effect, abbreviated new animal drug applications may be submitted in accordance with the provisions of section 514.55 and part 320 of title 21 of the Code of Federal Regulations and shall be considered as suitable for any drug which has been approved for safety and effectiveness under section 512(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b(c)] before the date of enactment of this Act. If any such provision of section 514.55 or part 320 is inconsistent 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).

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(h)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360b(h)(3)], as added by subsection (a), and for which an approval of an application filed pursuant to section 512(b) or 517 of such Act [21 U.S.C. 360b(b) or 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(h)(3) for the drug not later than March 31, 2010.

“(c) Separate Report.—The reports required under section 512(h)(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(b)(4) of title 21, Code of Federal Regulations (as in effect on the date of enactment of this title).

DRUGS INTENDED FOR MINOR SPECIES AND MINOR USES

Section 2(f) of Pub. L. 104–250 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

Section 6(c) of Pub. L. 104–250 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."

§ 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 to establish special controls to provide such assurance, but because it—

(I) is not purposed 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 purposed 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 purposed 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 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 title, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

(B) If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A))—

(i) which is sufficient to determine the effectiveness of a device, and

(ii) from which it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device,

then, for purposes of this section and sections 360d and 360e of this title, the Secretary may authorize the effectiveness of the device to be determined on the basis of such evidence.

(C) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 360e of this title has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

(D)(i) The Secretary, upon the written request of any person intending to submit an application under section 360e of this title, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to demonstrate for purposes of approval of an application the effectiveness of a device for the conditions of use proposed by such person. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

(ii) Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.

(iii) The determination of the Secretary with respect to the specification of valid scientific evidence under clauses (i) and (ii) shall be binding upon the Secretary, unless such determination by the Secretary could be contrary to the public health.

(b) Classification panels

(1) For purposes of—

(A) determining which devices intended for human use should be subject to the requirements of general controls, performance standards, or premarket approval, and

(B) providing notice to the manufacturers and importers of such devices to enable them to prepare for the application of such requirements to devices manufactured or imported by them,

the Secretary shall classify all such devices (other than devices classified by subsection (f) of this section) into the classes established by subsection (a) of this section. For the purpose of securing recommendations with respect to the classification of devices, the Secretary shall establish panels of experts or use panels of experts established before May 28, 1976, or both. Section 14 of the Federal Advisory Committee Act shall not apply to the duration of a panel established under this paragraph.

(2) The Secretary shall appoint to each panel established under paragraph (1) persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be
referred to the panel and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices. The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. In addition, each panel shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter may be a member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(3) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day so engaged, including traveltime; and while so serving away from their homes or regular places of business each member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, for persons in the Government service employed intermittently.

(4) The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

(5) Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

(6)(A) Any person whose device is specifically the subject of review by a classification panel shall—

(i) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5) as the Secretary;

(ii) the opportunity to submit, for review by a classification panel, information that is based on the data or information provided in the application submitted under section 360e of this title by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel; and

(iii) the same opportunity as the Secretary to participate in meetings of the panel.

(B) Any meetings of a classification panel shall provide adequate time for initial presentations and for response to any differing views by persons whose devices are specifically the subject of a classification panel review, and shall encourage free and open participation by all interested persons.

(7) After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 360e(d)(2) of this title, and shall notify the affected persons of the decision in writing, and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

(8) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.

(c) Classification panel organization and operation

(1) The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use are used. The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (b) of this section for its review and for its recommendation respecting the classification of the device. The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews and recommendations. In making their reviews and recommendations, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

(2)(A) Upon completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs (B) and (C), submit to the Secretary its recommendation for the classification of the device. Any such recommendation shall (i) contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made, and (ii) to the extent practicable, include a recommendation for the assignment of a priority for the application of the requirements of section 360d or 360e of this title to a device recommended to be classified in class II or class III.

(B) A recommendation of a panel for the classification of a device in class I shall include a recommendation as to whether the device should be exempted from the requirements of section 360, 360i, or 360j(f) of this title.

(C) In the case of a device which has been referred under paragraph (1) to a panel, and which—

(i) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life, and

(ii)(I) has been introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or

(II) is within a type of device which was so introduced or delivered before such date and is substantially equivalent to another device within that type,

such panel shall recommend to the Secretary that the device be classified in class III unless
the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.

(3) The panels shall submit to the Secretary within one year of the date funds are first appropriated for the implementation of this section their recommendations respecting all devices of a type introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976.

d) Panel recommendation; publication; priorities

(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel’s recommendation and a proposed regulation classifying such device and shall provide interested persons an opportunity to submit comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

(2)(A) A regulation under paragraph (1) classifying a device in class I shall prescribe which, if any, of the requirements of section 360, 360i, or 360j(f) of this title shall not apply to the device. A regulation which makes a requirement of section 360, 360i, or 360j(f) of this title inapplicable to a device shall be accompanied by a statement of the reasons of the Secretary for making such requirement inapplicable.

(B) A device described in subsection (c)(2)(C) of this section shall be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. A proposed regulation under paragraph (1) classifying a device in a class other than class III shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying such device in such class and an identification of the risks to health (if any) presented by such device.

(3) In the case of devices classified in class II and devices classified under this subsection in class III and described in section 360e(b)(1) of this title the Secretary may establish priorities which, in his discretion, shall be used in applying sections 360d and 360e of this title, as appropriate, to such devices.

e) Classification changes

(1) Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (A) change such device’s classification, and (B) revoke, because of the change in classification, any regulation or requirement in effect under section 360d or 360e of this title with respect to such device. In the promulgation of such a regulation respecting a device’s classification, the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) of this section a recommendation respecting the proposed change in the device’s classification and shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change. A regulation under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 360d of this title for such device.

(f) Initial classification and reclassification of certain devices

(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III unless—

(A) the device—

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b) of this section, or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type, or

(B) the Secretary in response to a petition submitted under paragraph (3) has classified such device in class I or II.

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) or (3) classifying the device in class I or II.

(2)(A) Any person who submits a report under section 360(k) of this title for a type of device that has not been previously classified under this chapter, and that is classified into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1) of this section. The person may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

(B)(i) Not later than 60 days after the date of the submission of the request under subparagraph (A), the Secretary shall by written order classify the device involved. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device
classified under this paragraph shall be a predi-
cate device for determining substantial equiva-
lence under paragraph (1).
(ii) A device that remains in class III under
this subparagraph shall be deemed to be adulter-
ated within the meaning of section 351(f)(1)(B)
of this title until approved under section 360e of
this title and exempted from such approval under
section 360(g) of this title.
(C) Within 30 days after the issuance of an
order classifying a device under this paragraph,
the Secretary shall publish a notice in the Fed-
eral Register announcing such classification.
(3)(A) The Secretary may initiate the reclassi-
ﬁcation of a device classiﬁed into class III under
paragraph (1) of this subsection or the manufac-
turer or importer of a device classiﬁed under
paragraph (1) may petition the Secretary (in
such form and manner as he shall prescribe) for
the issuance of an order classifying the device in
class I or class II. Within thirty days of the fil-
ing of such a petition, the Secretary shall notify
the petitioner of any deﬁciencies in the petition
which prevent the Secretary from making a de-
cision on the petition.
(B)(i) Upon determining that a petition does
not contain any deﬁciency which prevents the
Secretary from making a decision on the peti-
tion, the Secretary may for good cause shown
refer the petition to an appropriate panel estab-
lished or authorized to be used under subsection
(b) of this section. A panel to which such a peti-
tion has been referred shall not later than ninety
days after the referral of the petition make a
recommendation to the Secretary respecting ap-
proval or denial of the petition. Any such rec-
ommendation shall contain (I) a summary of the
reasons for the recommendation, (II) a summary
of the data upon which the recommendation is
based, and (III) an identiﬁcation of the risks to
health (if any) presented by the device with re-
spect to which the petition was ﬁled. In the case
of a petition for a device which is intended to be
implanted in the human body or which is pur-
ported or represented to be for a use in support-
ing or sustaining human life, the panel shall rec-
ommend that the petition be denied unless the
panel determines that the classiﬁcation in class
III of the device is not necessary to provide rea-
sonable assurance of its safety and effectiveness.
If the panel recommends that such petition be
approved, it shall in its recommendation to the
Secretary set forth its reasons for such recom-
mandation.
(ii) The requirements of paragraphs (1) and
(2) of subsection (c) of this section (relating to op-
opportunities for submission of data and views and
recommendations respecting priorities and ex-
emptions from sections 360, 360i, and 360(j) of
this title) shall apply with respect to consid-
eration by panels of petitions submitted under
subparagraph (A).
(C)(i) Within ninety days from the date the
Secretary receives the recommendation of a
panel respecting a petition (but not later than
210 days after the ﬁling of such petition) the
Secretary shall by order deny or approve the pe-
tition. If the Secretary approves the petition,
the Secretary shall order the classiﬁcation of
the device into class I or class II in accordance
with the criteria prescribed by subsection
(a)(1)(A) or (a)(1)(B) of this section. In the case of
a petition for a device which is intended to be
implanted in the human body or which is pur-
ported or represented to be for a use in support-
ing or sustaining human life, the Secretary shall
deny the petition unless the Secretary deter-
mines that the classiﬁcation in class III of the
device is not necessary to provide reasonable as-
surance of its safety and effectiveness. An order
approving such petition shall be accompanied by
a full statement of the reasons of the Secretary
and documentation and data for approving the peti-
tion and an identiﬁcation of the risks to health
(if any) presented by the device to which such order applies.
(ii) The requirements of paragraphs (1) and
(2)(A) of subsection (d) of this section (relating
to publication of recommendations, opportunity
for submission of comments, and exemption
from sections 360, 360i, and 360(j) of this title)
shall apply with respect to action by the Sec-
retary on petitions submitted under subpara-
graph (A).
(4) If a manufacturer reports to the Secretary
under section 360(k) of this title that a device is
substantially equivalent to another device—
(A) which the Secretary has classiﬁed as a
class III device under subsection (b) of this
section,
(B) which was introduced or delivered for in-
duction into interstate commerce for com-
mercial distribution before December 1, 1990,
and
(C) for which no ﬁnal regulation requiring
premarket approval has been promulgated
under section 360e(b) of this title,
the manufacturer shall certify to the Secretary
that the manufacturer has conducted a reason-
able search of all information known or other-
wise available to the manufacturer respecting
such other device and has included in the report
under section 360(k) of this title a summary of
and a citation to all adverse safety and efﬁc-
civeness data respecting such other device and
respecting the device for which the section
360(k) report is being made and which has not
been submitted to the Secretary under section
360i of this title. The Secretary may require the
manufacturer to submit the adverse safety and
effectiveness data described in the report.
(3) The Secretary may not withhold a deter-
mination of the initial classiﬁcation of a device
under paragraph (1) because of a failure to com-
ply with any provision of this chapter unrelated
to a substantial equivalence decision, including
a ﬁnding that the facility in which the device is
manufactured is not in compliance with good
manufacturing requirements as set forth in reg-
ulations of the Secretary under section 360(f) of
this title (other than a ﬁnding that there is a
substantial likelihood that the failure to comply
with such regulations will potentially present a
serious risk to human health).
(g) Information
Within sixty days of the receipt of a written
request of any person for information respecting
the class in which a device has been classiﬁed or
the requirements applicable to a device under
this chapter, the Secretary shall provide such
person a written statement of the classiﬁcation
(ii) The responsibilities of the Director under this subparagraph may not be delegated.

(F) Not later than 270 days after November 21, 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) of this section or section 360(k) of this title.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(E) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 360(k) of this title. However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the “Director”) may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—

(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall—

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director’s concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(F) Not later than 270 days after November 21, 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) of this section or section 360(k) of this title.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

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(E) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 360(k) of this title. However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the “Director”) may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—

(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall—

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director’s concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(F) Not later than 270 days after November 21, 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) of this section or section 360(k) of this title.

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(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall—

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director’s concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(F) Not later than 270 days after November 21, 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) of this section or section 360(k) of this title.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(E) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 360(k) of this title. However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the “Director”) may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—

(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall—

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director’s concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(F) Not later than 270 days after November 21, 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) of this section or section 360(k) of this title.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(E) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 360(k) of this title. However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the “Director”) may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—

(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall—

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director’s concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(F) Not later than 270 days after November 21, 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) of this section or section 360(k) of this title.
REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (b)(1), (8), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, as amended, which is set out in the Appendix to Title 5, Government Organization and Employees.

AMENDMENTS

2002—Subsec. (1)(A)(iv). Pub. L. 107–250 struck out cl. (iv) which read as follows: ‘‘This subparagraph has no legal effect after the expiration of the five-year period beginning on November 21, 1997.’’


Subsec. (a)(3)(C), (D). Pub. L. 105–115, § 205(a), added subpars. (C) and (D).

Subsec. (b)(5) to (8). Pub. L. 105–115, § 208, added pars. (5) to (8).


Subsec. (f)(2) to (4). Pub. L. 105–115, § 207(2), (3), added par. (2) and redesignated former pars. (2) and (3) as (3) and (4), respectively.


Subsec. (g)(1)(A)(i), Pub. L. 105–115, § 206(c)(5), substituted ‘‘appropriate clinical or scientific data’’ for ‘‘clinical data’’, inserted ‘‘or a person accredited under section 306m of this title’’ after ‘‘Secretary’’, and substituted ‘‘effectiveness’’ for ‘‘efficacy’’.

Subsec. (i)(1)(C), (D). Pub. L. 105–115, § 205(b), added subpars. (C) to (E).


1998—Subsec. (b)(3). Pub. L. 103–80 substituted ‘‘5073(b)’’ for ‘‘5073(c)’’.

Subsec. (b)(3). Pub. L. 103–300 substituted clauses (i) to (ii) as subpars. (A) to (C), respectively, and substituted ‘‘the section 360(k) report’’ for ‘‘the 360(k) report’’ in closing provisions.


A device which cannot be classified as a class I device because the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of such lens, including clinical and preclinical data if deemed necessary by the Secretary.

Subsec. (a)(1)(B). Pub. L. 101–629, § 5(a)(2), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: ‘‘CLASS II, PERFORMANCE STANDARDS.—A device which cannot be classified as a class I device because the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of such lens, including clinical and preclinical data if deemed necessary by the Secretary.’’

Subsec. (a)(1)(C)(i). Pub. L. 101–629, § 5(a)(3), amended cl. (i) generally. Prior to amendment, cl. (i) read as follows: ‘‘it (I) cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title are sufficient to provide reasonable assurance of its safety and effectiveness, and’’;

Subsec. (e). Pub. L. 101–629, § 5(b), designated existing provisions as par. (1), redesignated cls. (1) and (2) as (A) and (B), respectively, and added par. (2).


Subsec. (f)(1)(A). Pub. L. 101–629, § 5(c)(1), substituted ‘‘The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer’’ for ‘‘The manufacturer’’.

Subsec. (f)(2)(B)(i). Pub. L. 101–629, § 18(a), substituted ‘‘the Secretary may for good cause shown’’ for ‘‘the Secretary shall’’.


EFFECTIVE DATE OF 1997 AMENDMENT


SHORT TITLE OF 1976 AMENDMENT

Pub. L. 94–295, § 1(a), May 28, 1976, 90 Stat. 529, provided that: ‘‘This Act [enacting sections 360c to 360k, 379, and 379a of this title and section 3512 of Title 42, The Public Health and Welfare, and amending sections 331, 334, 351, 352, 358, 360, 374, 379a, and 381 of this title and section 55 of Title 15, Commerce and Trade] may be cited as the ‘Medical Device Amendments of 1976’.’’

REGULATIONS

Section 12(b) of Pub. L. 101–629 provided that: ‘‘Within 12 months of the date of the enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall issue regulations establishing the requirements of the summaries under section 513(i)(3) of the Federal Food, Drug, and Cosmeti Act [21 U.S.C. 360(c)(3)], as added by the amendment made by subsection (a).’’

DAILY WEAR SOFT OR DAILY WEAR NONHYDROPHILIC PLASTIC CONTACT LENSES

Section 4(b)(3) of Pub. L. 101–629 provided that: ‘‘(A) Notwithstanding section 520(i)(5) of the Federal Food, Drug, and Cosmeti Act [21 U.S.C. 360(i)(5)], the Secretary of Health and Human Services shall not retain any daily wear soft or daily wear nonhydrophilic plastic contact lens in class III under such Act [this chapter] unless the Secretary finds that it meets the criteria set forth in section 513(a)(1)(C) of such Act [21 U.S.C. 360(a)(1)(C)]. The finding and the grounds for the finding shall be published in the Federal Register. For any such lens, the Secretary shall make the determination respecting reclassification required in section 520(i)(5)(B) of such Act within 24 months of the date of the enactment of this paragraph [Nov. 28, 1990].’’

‘‘(B) The Secretary of Health and Human Services may by notice published in the Federal Register extend the two-year period prescribed by section 513(e) for a classification change.’’

‘‘(C) Before classifying a lens in class II pursuant to subparagraph (A), the Secretary of Health and Human Services shall publish a section 513(a)(1)(C) of such Act [21 U.S.C. 360(a)(1)(C)] which assures that appropriate regulatory safeguards are in effect which provide reasonable assurance of the safety and effectiveness of such lens, including clinical and preclinical data if deemed necessary by the Secretary.

‘‘(D) Prior to classifying a lens in class II pursuant to subparagraph (A), the Secretary shall assure that appropriate regulatory safeguards are in effect which provide reasonable assurance of the safety and effectiveness of such lens, including clinical and preclinical data if deemed necessary by the Secretary.

‘‘(E) Any person adversely affected by a final regulation under this paragraph revising the classification of a lens may challenge the revision of the classification of such lens only by filing a petition under section 513(e) for a classification change.’’


§ 360d. Performance standards

(a) Reasonable assurance of safe and effective performance; periodic evaluation

(1) The special controls required by section 360c(a)(1)(B) of this title shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under subsection (b) of this section if the device has been reclassified as a class II device under a regulation under section 360c(e) of this title but such regulation provides that the reclassification is not to take effect until the effective date of such a standard for the device.

(2) A performance standard established under subsection (b) of this section for a device shall—

(A) shall include provisions to provide reasonable assurance of its safe and effective performance;

(B) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.

(3) The Secretary shall provide for periodic evaluation of performance standards established under subsection (b) of this section to determine if such standards should be changed to reflect new medical, scientific, or other technological data.

(b) Establishment of a standard

(1) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, or consumer organizations who in his judgment can make a significant contribution.

(B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device shall—

(i) set forth a finding with supporting justification that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device,

(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate;

(iii) invite interested persons to submit to the Secretary, within 30 days of the publication of the notice, requests for changes in the classification of the device pursuant to section 360c(e) of this title based on new information relevant to the classification, and

(iv) invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Secretary.

(C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

(D) The Secretary shall provide for a comment period of not less than 60 days.

(2) If, after publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the classification of the device, the Secretary shall, within 60 days of the publication of the notice, after consultation with the appropriate panel under section 360c of this title, either deny the request or give notice of an intent to initiate such change under section 360c(e) of this title.

(3) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory