made the finding and published the finding required by subparagraph (A) within 36 months of the date of the enactment of this subparagraph [Nov. 28, 1990], the Secretary shall issue an order placing the lens in class II.

''(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.''

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

§ 360c–1. Reporting

The Secretary of Health and Human Services shall annually post on the Internet Web site of the Food and Drug Administration—

(1) the number and type of class I and class II devices reclassified as class II or class III in the previous calendar year under section 360c(e)(1) of this title;

(2) the number and type of class II and class III devices reclassified as class I or class II in the previous calendar year under such section 360c(e)(1) of this title; and

(3) the number and type of devices reclassified in the previous calendar year under section 360e of this title.

(Pub. L. 112–144, title VI, § 608(c), July 9, 2012, 126 Stat. 1059.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Food and Drug Administration Safety and Innovation Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 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) if the device has been reclassified as a class II device under an administrative order under section 360c(e) of this title (or a regulation promulgated under such section prior to July 9, 2012) but such order (or 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) for a device—

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

(B) shall, where necessary to provide reasonable assurance of its safe and effective performance, include—

(i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems,

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the device to the standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) by the Secretary or by another person at the direction of the Secretary,

(iii) provisions for the measurement of the performance characteristics of the device,

(iv) provisions requiring that the results of each or of certain of the tests of the device required to be made under clause (ii) show that the device is in conformity with the portions of the standard for which the test or tests were required, and

(v) a provision requiring that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 360j(e) of this title; and

(C) 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) to determine if such standards should be changed to reflect new medical, scientific, or other technological data.

(4) In carrying out his duties under this subsection and subsection (b), the Secretary shall, to the maximum extent practicable—

(A) use personnel, facilities, and other technical support available in other Federal agencies,

(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities, and

(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) Establishment of a standard

(1)(A) 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.

(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)(A) 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 committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (1), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

(4)(A) The Secretary, upon his own initiative or upon petition of an interested person may by regulation, promulgated in accordance with the requirements of paragraphs (1), (2), and (3)(B) of this subsection, amend or revoke a performance standard.

(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

(5)(A) The Secretary—

(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

(ii) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,

to an advisory committee of experts, established pursuant to subparagraph (B), for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

(B) The Secretary shall establish advisory committees (which may not be panels under section 360c of this title) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day (including traveltime) they are so engaged; 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. The Secretary shall designate one of the members of each advisory committee to serve as chairman thereof. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(c) Recognition of standard

(1)(A) In addition to establishing a performance standard under this section, the Secretary shall, by publication in the Federal Register (or, with respect to a susceptibility test interpretive criteria standard under section 360a–2 of this title, by posting on the Interpretive Criteria Website in accordance with such section), recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement under this chapter to which such standard is applicable.

(B) If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this chapter.

(C)(i) Any person may submit a request for recognition under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard organization.[1]

(ii) Not later than 60 calendar days after the Secretary receives such a request, the Secretary shall—

(I) make a determination to recognize all, part, or none of the standard that is the subject of the request; and

(II) issue to the person who submitted such request a response in writing that states the Secretary's rationale for that determination, including the scientific, technical, regulatory, or other basis for such determination.

(iii) The Secretary shall make a response issued under clause (ii)(II) publicly available, in such a manner as the Secretary determines appropriate.

(iv) The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under clause (ii)(I), in accordance with subparagraph (A).

(D) The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, the rationale for recognition under subparagraph (A) of all, part, or none of a standard, including the scientific, technical, regulatory, or other basis for the decision regarding such recognition.

(2) The Secretary may withdraw such recognition of a standard through publication of a notice in the Federal Register if the Secretary determines that the standard is no longer appropriate for meeting a requirement regarding devices under this chapter.

(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

(C) A person making a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of two years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer.

(4) The Secretary shall provide to all employees of the Food and Drug Administration who review premarket submissions for devices periodic training on the concept and use of recognized standards for purposes of meeting a premarket submission requirement or other applicable requirement under this chapter, including standards relevant to an employee's area of device review.

(d) Accreditation scheme for conformity assessment

(1) In general

The Secretary shall establish a program under which—

(A) testing laboratories meeting criteria specified in guidance by the Secretary may be accredited, by accreditation bodies meeting criteria specified in guidance by the Secretary, to conduct testing to support the assessment of the conformity of a device to certain standards recognized under this section; and

(B) subject to paragraph (2), results from tests conducted to support the assessment of conformity of devices as described in subparagraph (A) conducted by testing laboratories accredited pursuant to this subsection shall be accepted by the Secretary for purposes of demonstrating such conformity unless the Secretary finds that certain results of such tests should not be so accepted.

(2) Secretarial review of accredited laboratory results

The Secretary may—

(A) review the results of tests conducted by testing laboratories accredited pursuant

[1] So in original. Probably should be ''standard development organization.''

to this subsection, including by conducting periodic audits of such results or of the processes of accredited bodies or testing laboratories;

(B) following such review, take additional measures under this chapter, as the Secretary determines appropriate, such as—

(i) suspension or withdrawal of accreditation of a testing laboratory or recognition of an accreditation body under paragraph (1)(A); or

(ii) requesting additional information with respect to a device; and

(C) if the Secretary becomes aware of information materially bearing on the safety or effectiveness of a device for which an assessment of conformity was supported by testing conducted by a testing laboratory accredited under this subsection, take such additional measures under this chapter, as the Secretary determines appropriate, such as—

(i) suspension or withdrawal of accreditation of a testing laboratory or recognition of an accreditation body under paragraph (1)(A); or

(ii) requesting additional information with regard to such device.

(3) Report

The Secretary shall make available on the internet website of the Food and Drug Administration an annual report on the progress of the program under this subsection.

(June 25, 1938, ch. 675, § 514, as added Pub. L. 94–295, § 2, May 28, 1976, 90 Stat. 546; amended Pub. L. 94–460, title III, § 304, Oct. 8, 1976, 90 Stat. 1960; Pub. L. 101–629, §§ 6(a), (b)(1), 18(b), Nov. 28, 1990, 104 Stat. 4519, 4528; Pub. L. 102–300, § 6(g), June 16, 1992, 106 Stat. 241; Pub. L. 103–80, § 4(a)(1), Aug. 13, 1993, 107 Stat. 779; Pub. L. 105–115, title II, § 204(a), (d), Nov. 21, 1997, 111 Stat. 2335, 2336; Pub. L. 112–144, title VI, § 608(a)(2)(B), July 9, 2012, 126 Stat. 1056; Pub. L. 114–255, div. A, title III, §§ 3044(b)(3), 3053(a), Dec. 13, 2016, 130 Stat. 1121, 1125; Pub. L. 115–52, title II, § 205(a), Aug. 18, 2017, 131 Stat. 1016; Pub. L. 117–180, div. F, title II, § 2005, Sept. 30, 2022, 136 Stat. 2153.)

Editorial Notes

AMENDMENTS

2022—Subsec. (d). Pub. L. 117–180 amended subsec. (d) generally. Prior to amendment, subsec. (d) related to a pilot program for accrediting laboratories to assess device conformance.

2017—Subsec. (d). Pub. L. 115–52 added subsec. (d).

2016—Subsec. (c)(1)(A). Pub. L. 114–255, § 3044(b)(3), inserted ''(or, with respect to a susceptibility test interpretive criteria standard under section 360a–2 of this title, by posting on the Interpretive Criteria Website in accordance with such section)'' after ''the Secretary shall, by publication in the Federal Register''.

Subsec. (c)(1)(C), (D). Pub. L. 114–255, § 3053(a)(1), added subpars. (C) and (D).

Subsec. (c)(4). Pub. L. 114–255, § 3053(a)(2), added par. (4).

2012—Subsec. (a)(1). Pub. L. 112–144 substituted ''under an administrative order under section 360c(e) of this title (or a regulation promulgated under such section prior to July 9, 2012) but such order (or regulation)'' for ''under a regulation under section 360c(e) of this title but such regulation''.

1997—Subsec. (a)(1). Pub. L. 105–115, § 204(d)(1), substituted ''under subsection (b)'' for ''under this section''.

Subsec. (a)(2). Pub. L. 105–115, § 204(d)(2), substituted ''under subsection (b)'' for ''under this section'' in introductory provisions.

Subsec. (a)(3). Pub. L. 105–115, § 204(d)(3), substituted ''under subsection (b)'' for ''under this section''.

Subsec. (a)(4). Pub. L. 105–115, § 204(d)(4), substituted ''this subsection and subsection (b)'' for ''this section'' in introductory provisions.

Subsec. (c). Pub. L. 105–115, § 204(a), added subsec. (c).

1993—Subsec. (b)(4)(B), (5)(A)(ii). Pub. L. 103–80 amended directory language of Pub. L. 101–619, § 18(b), identical to amendment by Pub. L. 102–300, § 6(g)(1). See 1992 and 1990 Amendment notes below.

1992—Subsec. (b)(4)(B), (5)(A)(ii). Pub. L. 102–300 made technical corrections to directory language of Pub. L. 101–629, § 18(b)(1), (2). See 1990 Amendment note below.

1990—Subsec. (a)(1). Pub. L. 101–629, § 6(a)(1), substituted ''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.'' for ''The Secretary may by regulation, promulgated in accordance with this section, establish a performance standard for a class II device.''

Subsec. (b). Pub. L. 101–629, § 6(a)(2), (3), redesignated subsec. (g) as (b) and struck out former subsec. (b) which read as follows:

''(1) A proceeding for the development of a performance standard for a device shall be initiated by the Secretary by the publication in the Federal Register of notice of the opportunity to submit to the Secretary a request (within fifteen days of the date of the publication of the notice) for a change in the classification of the device based on new information relevant to its classification.

''(2) If, after publication of a notice pursuant to paragraph (1) the Secretary receives a request for a change in the device's classification, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 360c of this title, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 360c(e) of this title.''

Subsec. (b)(1), (2). Pub. L. 101–629, § 6(a)(4), amended pars. (1) and (2) generally. Prior to amendment, pars. (1) and (2) read as follows:

''(1)(A) After publication pursuant to subsection (c) of this section of a notice respecting a performance standard for a device, the Secretary shall either—

''(i) publish, in the Federal Register in a notice of proposed rulemaking, a proposed performance standard for the device (I) developed by an offeror under such notice and accepted by the Secretary, (II) developed under subsection (c)(4) of this section, (III) accepted by the Secretary under subsection (d) of this section, or (IV) developed by him under subsection (f) of this section, or

''(ii) issue a notice in the Federal Register that the proceeding is terminated together with the reasons for such termination.

''(B) If the Secretary issues under subparagraph (A)(ii) a notice of termination of a proceeding to establish a performance standard for a device, he shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

''(2) A notice of proposed rulemaking for the establishment of a performance standard for a device published under paragraph (1)(A)(i) shall set forth proposed findings with respect to the degree of the risk of illness or injury designed to be eliminated or reduced by the proposed standard and the benefit to the public from the device.''

Subsec. (b)(3)(A)(i). Pub. L. 101–629, §6(b)(1)(A), substituted ''paragraph (1)'' for ''paragraph (2)''.

Subsec. (b)(4)(A). Pub. L. 101–629, §6(b)(1)(B), substituted ''paragraphs (1), (2), and (3)(B)'' for ''paragraphs (2) and (3)(B)''.

Subsec. (b)(4)(B). Pub. L. 101–629, §18(b)(1), as amended by Pub. L. 102–300, §6(g)(1), (2), and Pub. L. 103–80, §4(a)(1), struck out '', after affording all interested persons an opportunity for an informal hearing,'' after ''if he determines''.

Subsec. (b)(5)(A)(ii). Pub. L. 101–629, §18(b)(2), as amended by Pub. L. 102–300, §6(g)(1), (3), and Pub. L. 103–80, §4(a)(1), substituted ''which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,'' for ''unless the Secretary finds the request to be without good cause or the request is made after the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,''.

Subsecs. (c) to (f). Pub. L. 101–629, §6(a)(2), struck out subsec. (c) relating to invitations for standards, subsec. (d) relating to acceptance of certain existing standards, subsec. (e) relating to acceptance of offers to develop standards, and subsec. (f) relating to development of standards by the Secretary after publication of notice inviting submissions or offers of standards.

Subsec. (g). Pub. L. 101–629, §6(a)(3), redesignated subsec. (g) as (b).

1976—Subsec. (a). Pub. L. 94–460 redesignated pars. (4) and (5) as (3) and (4), respectively. Section as originally enacted contained no par. (3).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2022 AMENDMENT

Pub. L. 117–180, div. F, title II, §2008, Sept. 30, 2022, 136 Stat. 2154, provided that: ''The amendments made by this title [amending this section and sections 360m and 379i to 379j–1 of this title and repealing provisions set out as notes under sections 379i and 379j–1 of this title] shall take effect on October 1, 2022, or the date of the enactment of this Act [Sept. 30, 2022], whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.) shall be assessed for all submissions listed in section 738(a)(2)(A) of such Act [21 U.S.C. 379j(a)(2)(A)] received on or after October 1, 2022, regardless of the date of the enactment of this Act.''

EFFECTIVE DATE OF 2017 AMENDMENT

Amendment by Pub. L. 115–52 effective Oct. 1, 2017, with fees under subpart 3 of part C of subchapter VII of this chapter to be assessed for all submissions listed in section 379j(a)(2)(A) of this title received on or after Oct. 1, 2017, see section 209 of Pub. L. 115–52, set out as a note under section 379i of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of this title.

CONSTRUCTION OF 2016 AMENDMENT

Nothing in amendment by section 3044(b)(3) of Pub. L. 114–255 to be construed to restrict the prescribing of antimicrobial drugs or other products, including drugs approved under section 356(h) of this title, by health care professionals, or to limit the practice of health care, see section 3043 of Pub. L. 114–255, set out as a note under section 356 of this title.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees in existence on Jan. 5, 1973, to terminate not later than the expiration of the 2-year period following Jan. 5, 1973, and advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided by law. See section 1013 of Title 5, Government Organization and Employees.

GUIDANCE

Pub. L. 114–255, div. A, title III, §3053(b), Dec. 13, 2016, 130 Stat. 1125, provided that: ''The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review and update, if necessary, previously published guidance and standard operating procedures identifying the principles for recognizing standards, and for withdrawing the recognition of standards, under section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)), taking into account the experience with and reliance on a standard by foreign regulatory authorities and the device industry, and whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.''

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

§ 360e. Premarket approval

(a) General requirement

A class III device—

(1) which is subject to an order issued under subsection (b) (or a regulation promulgated under such subsection prior to July 9, 2012); or

(2) which is a class III device because of section 360c(f) of this title,

is required to have, unless exempt under section 360j(g) of this title, an approval under this section of an application for premarket approval or, as applicable, an approval under subsection (c)(2) of a report seeking premarket approval.

(b) Order to require premarket approval

(1) In the case of a class III device which—

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type,

the Secretary shall by administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 360c(b) of this title, and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, require that such device have an approval under this section of an application for premarket approval. Authority to issue such administrative order shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.

(2) A proposed order required under paragraph (1) shall contain—