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PART V

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

MEDICAL DEVICES

Proposed Procedures for Development of Standards

[4110-03]

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Food and Drug Administration

[21 CFR Parts 16, 20, 809, 861]

[Docket No. 78N-0002]

MEDICAL DEVICES

Proposed Procedures for Development of Standards

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The agency proposes to prescribe procedures for the initiation, development, establishment, amendment, and revocation of performance standards for medical devices including in vitro diagnostic products. The proposed rule would implement section 514 of the Federal Food, Drug, and Cosmetic Act. FDA is also amending the in vitro diagnostic products regulation to revoke the special procedures for establishing, amending or repealing standards and conform the regulations to the Medical Device Amendment of 1976.

DATES: Written comments by September 25, 1978. It is proposed that the regulation become effective 30 days after publication of the final order in the FEDERAL REGISTER. These amendments will be effective upon the effective date of the final regulation.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James McCue, Bureau of Medical Devices (HFK-310), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7222.

SUPPLEMENTARY INFORMATION: The Medical Device Amendments of 1976 ("the amendments") (Pub. L. 94-295), amending the Federal Food, Drug, and Cosmetic Act ("the act"), became law on May 28, 1976. Included in the amendments is new section 514 (21 U.S.C. 360d), which sets forth the requirements for performance standards. Section 513 of the act (21 U.S.C. 360c), describing the process for classifying medical devices, states that performance standards are required for devices for which general controls alone are insufficient to provide reasonable assurance of safety and effectiveness and for which sufficient information is available to establish a performance standard to provide such assurance. (See the classification procedures proposal published in the FEDERAL REGISTER of September 13, 1977 (42 FR 46028) for further explanation of the classification process and the determination of safety and effectiveness).

A device classified into class II must conform to an applicable performance standard promulgated in a regulation establishing the standard. Regulations establishing performance standards may not take effect before 1 year after the date of their publication in the FEDERAL REGISTER unless (1) the Commissioner determines that an earlier effective date is in the public interest, or (2) such standard has been established for a device which, upon the effective date of the standard, has been reclassified from class III to class II. Effective dates will be established so as to minimize economic loss consistent with the public health and safety.

Devices for which performance standards are required, however, will also continue to be subject to the general provisions of the act, as under class I. These provisions include controls prohibiting adulterated or misbranded devices; registration provisions; premarket notification; banned device provisions; defect notification and other remedies; records and reports; restrictions on sale, distribution, and use; and good manufacturing practices.

Proposed part 861 explains the requirements for the development of standards set forth in section 514 of the act. Although that section describes the process in detail, the Commissioner believes that further elaboration in the form of a procedural regulation is necessary to facilitate the initiation, development, establishment, amendment, and revocation of performance standards. In the future, FDA may publish a notice further describing the agency's policy concerning development, and FDA acceptance, of voluntary standards and how this policy relates to the development of performance standards under proposed part 861.

HISTORY OF STANDARDS DEVELOPMENT

The Food and Drug Administration (FDA) has been engaged for several years in activities designed to encourage the development of voluntary performance standards for medical devices. A review of FDA medical device performance standards activities was described in a notice published in the FEDERAL REGISTER of August 12, 1976 (41 FR 34099). This notice explained that FDA has emphasized development of standards for currently marketed devices. Manufacturers could voluntarily use these standards in designing and manufacturing their products, and users of medical devices could rely upon such standards as guidelines for purchasing devices.

Prior to the amendments, standards procedures for medical devices which are in vitro diagnostic products had been governed by 21 CFR 809.30, which FDA proposes to revoke (although 21 CFR 809.10 relating to labeling of in vitro diagnostic products will remain in effect until further notice).

In accordance with the procedures of section 809.30, calls for data and information were published in the FEDERAL REGISTER as follows: 38 FR 13573, May 23, 1973, Detection of Measurement of Glucose or Total Sugars; November 2, 1973, 38 FR 30290, Calibrators for Quantitative Clinical Chemistry Analytical Procedures; March 8, 1974, 39 FR 9217, Measurement of Hemoglobin in Human Blood; April 16, 1975, 40 FR 17058, Nontreponemal Tests for Syphilis; September 18, 1975, 40 FR 43045, Antirubella Antibody Tests.

After reviewing the information received, standards development activities were initiated in cooperation with members of the FDA Diagnostic Products Advisory Committee, the Center for Disease Control (CDC), and the National Bureau of Standards (NBS).

On June 28, 1974 (39 FR 24136), FDA proposed a standard for products used to detect or measure glucose or total sugars. After considering comments received on the proposed standard, the standard was revised to include only those products intended for the quantitative measurement of glucose in plasma or serum. The revised standard, including an evaluation procedures document, will be made available to interested persons in the near future. In addition, the work on the other four standards is continuing and will also be made available upon completion. Further development of standards for in vitro diagnostic products will proceed according to section 514 of the act and procedures to be promulgated under Part 21 CFR 861.

Because voluntary standards help to assure the safety and effectiveness of marketed devices, FDA will continue to promote their use. Voluntary or privately recognized performance standards may serve as informal standards before FDA classifies the devices and during the development of formal standards under proposed part 861. Voluntary standards will be especially important for devices that are not candidates for immediate standards development under proposed part 861. Moreover, under proposed § 861.20 (21 CFR 861.20) voluntary standards may be the basis of subsequent formal FDA standards.

DESCRIPTION OF THE PROPOSED REGULATION

Proposed § 861.1 (21 CFR 861.1) sets forth the general purpose and scope of the standards procedures regulations.

Proposed § 861.5 describes how the Commissioner of Food and Drugs will solicit support in the development of performance standards from as broad a base of potentially interested persons as possible.

Proposed § 861.7 (21 CFR 861.7) sets forth specific requirements to be included in a performance standard if the Commissioner believes such provisions are necessary to assure the safety and effectiveness of the device:

1. Provisions concerning the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems;

2. Provisions for testing the device for safety and effectiveness;

3. Provisions for measuring the performance characteristics of the device;

4. Provisions requiring that the results of the tests of the device required to be made under item (2) show that the device conforms to the standard for which the tests were required;

5. A provision requiring that the sale and distribution of the device be restricted to the extent permissible under section 520(e) of the act;

6. Provisions for including in the labeling information on the installation, maintenance, operation, and use of the device.

Additional requirements may be necessary depending upon the nature of the device. While all of the requirements in proposed § 861.7 may not be required for every standard, the section provides a reasonably comprehensive list of the types of requirements that may be imposed.

Proposed § 861.7(b) requires that a performance standard include, where necessary to provide reasonable assurance of its safe and effective peformance, provisions concerning the design of the device. Although the term "performance standard" reflects a preference for standards that allow for the use of technological alternatives, the legislative history indicates that Congress intended that a standard include design-related requirements likely to assure safe and effective performance and to reduce human errors (H.R. Rep. No. 853, 94th Cong., 2d Sess. 26 (1976)).

Proposed § 861.7(f) requires, where necessary, that manufacturers certify that a device conforms to a standard. Manufacturers may certify conformity either by letter or by a tag or label affixed to the device or packaging for a device. The Commissioner may require that the certification be addressed to the ultimate user, to the Commissioner, or to both.

PROCEDURES FOR STANDARDS DEVELOPMENT AND PROMULGATION

Proposed § 861.20 provides a summary of the procedures by which a performance standard for a device is to be developed and promulgated.

Paragraph (d) of proposed § 861.20 describes the options available to the Commissioner in developing a standard. The Commissioner may:

1. Authorize another Federal agency to develop a standard;

2. Accept an existing standard as a proposd standard or as a basis upon which a proposed standard may be developed;

3. Accept one or more offers to develop a standard submitted in accordance with the requirements of proposd §§ 861.26 and 861.28 (21 CFR 861.26 and 861.28, respectively); or

4. Develop a proposed standard himself, using FDA expertise. In the interest of economy and better control over the standards development process and consistent with the provisions of sections 514(a)(5)(A) and 514(c)(4) of the act, the Commissioner would prefer the development of a standard by a Federal agency with appropriate personnel, expertise, and resources to develop the proposed standard.

The Commissioner will give priority to a standard that already exists, or that has been developed, issued, or adopted if he determines that such standard is based upon scientific data and information and has been subjected to adequate scientific consideration. The Commissioner will prefer such a standard only if he determines that it would adequately protect the public health.

Using the criteria specified in proposed §§ 861.26 and 861.28, the Commissioner will accept an offer or offers to develop a proposed standard only if he has neither authorized development of a standard by a Federal agency nor accepted an existing standard.

After considering all options, if no offers to develop a standard are submitted, if none is accepted because none satisfies the requirements of this proposed regulation, or if an offeror cannot, will not, or should not continue developing a standard, FDA may develop the standard under the procedures in proposed § 861.30(a) (21 CFR 861.30(a)). This authority is in addition to the authority of the Commissioner to develop a standard in lieu of accepting an offer to do so.

Proposed § 861.22 (21 CFR 861.22) describes the "invitation" process in detail, i.e., the process whereby the Commissioner invites any person (including any Federal agency) to submit an existing standard as a proposed performance standard or to offer to develop such a standard.

An invitation to submit or develop a proposed performance standard will include a statement of the risks associated with the device and a summary of data indicating the need to develop performance standard. The statement of risks may be a summary of the opinions of experts within FDA or outside the agency. The statement of risks will include, where available, references to published information about experience with the device. The summary of data upon which the need to develop a standard was determined will be sufficient to advise interested persons of the problems to be addressed by a performance standard. Both the statement of risks and the summary of data will include pertinent portions of the recommendations of classification panels with respect to the device and will list the characteristics of the device which necessitated the establishment of a performance standard.

The legislative history indicates that an invitation to submit or develop a proposed performance standard is not to be construed as a Federal procurement (H.R. Rep. No. 853, 94th Cong., 2d Sess. 26 (1976)). Therefore, an invitation will not be subject to the requirements of section 8 of the Small Business Act (15 U.S.C. 637) (relating to procurement contracts) or 41 U.S.C. 5 (relating to the requirement of advertisement before contracting).

The Food and Drug Administration has already developed or assisted in the development of performance standards for several medical devices. Under proposed § 861.24 (21 CFR 861.24), such standards may be accepted as proposed performance standards. As mentioned previously, several "voluntary" medical device standards have also been developed or are in the process of being developed by various standards—setting organizations. The Commissioner may accept a voluntary standard, wholly or partially, as a proposed performance standard or as the basis for such a standard, if he determines that it has been subjected to appropriate scientific consideration.

Proposed § 861.26 discusses the information that must accompany an offer to develop a proposed standard submitted in response to an invitation published pursuant to proposed § 861.22. The information required relates generally to the offeror's expertise, financial ability, potential conflicts of interest, the procedures the offeror will utilize in developing the standard, and environmental impact information regarding compliance with Federal and local laws. Such information will include plans for involving interested members of the public, a description of the facilities and

equipment to be used, time estimates and detailed schedules, testing methods, and a request for contribution if desired.

Under proposed § 861.26(a)(3), the Commissioner will require disclosure of potential conflicts of interest. In order to assure that only the offers of qualified persons are accepted, proposed § 861.26(a)(3) requires offerors and appropriate directors, consultants, and employees of offerors to submit relevant information about their financial stability, expertise, experience, and potential conflicts of interest (including financial interests in the device for which a proposed standard is to be developed or in the device industry generally, all current industrial or commercial affiliations, sources of research support, and companies in which they have financial interest). These disclosure requirements will permit the Commissioner to disqualify offerors whose efforts might be impeded by financial or other conflicts of interest. In instances in which more than one offer is submitted by technically competent persons, the Commissioner will prefer an offeror with no proprietary interest in the device for which a standard is to be developed.

The Commissioner may accept several offers to develop a proposed performance standard under §§ 861.24 and 861.26. The Commissioner may also take advantage of the expertise of several parties to develop portions of a standard that will then be utilized in promulgating a single cohesive document.

Proposed § 861.28 describes the process by which the Commissioner will accept offers to develop performance standards.

Propsed § 861.30 describes the requirements of the standards development process, including the important requirement that the public be encouraged to participate in the development of the standards. Also, a person developing a standard must provide the Commissioner with information on the course of the development effort. The developer must submit progress reports and must permit FDA to inspect its facility and developmental activities to enable the agency to make a progress evaluation.

Under proposed § 861.32 (21 CFR 861.32), the Commissioner may agree to contribute to an offeror's cost in developing a performance standard insofar as the contribution complies with Federal procurement regulations (41 CFR Part 1-15).

Proposed § 861.34 (21 CFR 861.34) provides for the amendment or revocation of standards. The rulemaking procedures of 21 CFR 10.40 apply to proposed § 861.34. Petitions for amendment or revocation must be in the form of citizen petitions as described in 21 CFR 10.30. In addition, the petition must identify the specific device and standard for which amendment or revocation is sought. Under proposed § 861.34(c), a proceeding to amend or revoke a standard will be subject to both review by an advisory committee established under proposed § 861.38 (21 CFR 861.38), if requested and granted, and to the effective date requirements of proposed § 861.36. A notice of proposed rulemaking to amend or revoke a standard will include information on the degree of risk or illness to be eliminated or reduced.

Proposed § 861.36 (21 CFR 861.36) sets forth the requirements regarding effective dates of establishment, amendment, and revocation of performance standards. The Commissioner will designate in effective date according to his best judgment after reviewing all available data; an economic impact statement, when prepared in the course of proposing a regulation, will serve as one of the bases for determining the effective date.

Proposed § 861.36(b) sets forth the general principle that a performance standard regulation may not take effect before 1 year after its date of publication because conformity to a standard may take some time. Congress intended the provisions requiring the Commissioner to consider economic factors in determining an effective date to allow depletion of inventories of class II devices which, while not conforming to newly promulgated standards, do not present a risk. Congress clearly intended to discourage stockpiling of nonconforming devices; however, because on their effective date, performance standards will apply to all devices in commercial channels. (H.R. Rep. No. 853, 94th Cong., 2d Sess. 30 (1976)).

Under proposed § 861.36(b), the Commissioner may accelerate the effective date when necessary to protect the public. If the standard applies to a device reclassified from the premarket approval category (class III) to class II, the effective date of the reclassification may coincide with the effective date of the standard.

Under proposed § 861.36(c), a proposed amendment to a standard may be made effective immediately upon its publication if it is determined, after an opportunity for an informal hearing is afforeded, that such action would be in the public interest. A device that does not conform to the amended standard, however, could continue to the marketed until final action is taken on the proposed amendment. This expedited approach is intended to stimulate desirable changes in products subject to standards without penalizing manufacturers of products on the market that conform to existing standards (H.R. Rep. No. 853, 94th Cong., 2d Sess. 30 (1976)).

Proposed § 861.38 provides that the Commissioner may refer a proposed regulation to an advisory committee, other than a classification panel established under section 513 of the act, for a report and recommendation on matters requiring scentific judgment. The legislative history indicates that Congress intended that the act's prohibition of the use of classification panels as standard-setting advisory committees not preclude the appointment of individual members of classification panels to any such advisory committees (H.R. Rep. No. 853, 94th Cong., 2d Sess. 30 (1976)).

Sections 809.30 through 809.35 (21 CFR 809.30—809.35) provide a procedure for establishing, amending, or repealing standards for in vitro products. Because of section 514 of the act (21 U.S.C. 360d), however, those procedures are inadequate and are not followed. Accordingly the Commissioner proposes to amend section 809 by revoking sections 809.30 through 809.35 and making other changes in part 809 to confrom with the revocation.

Proposed Effective Date

The Commissioner proposes to make the final regulation relating to this proposal effective 30 days after the date the final regulation is published in the Federal Register.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 501, 502, 513, 514, 701, 52 Stat. 1049-1051 as amended, 1055-1056 as amended, 90 Stat. 540-552 (21 U.S.C. 351, 352, 360c, 360d, 371)) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that chapter I of title 21 of the Code of Federal Regulations be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. In part 16, by adding new § 16.1(b)(31) as follows:

§ 16.1 Scope.

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(b) * * *

(31) Section 861.36, relating to an immediate effective date for proposed

regulations amending performance standards for medical device products.

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PART 20—PUBLIC INFORMATION

2. In part 20, by adding new § 20.100(c)(32) as follows:

§ 20.100 Applicability; cross-reference to other regulations.

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(c) * * *

(32) Data and information submitted in offers to develop a proposed performance standard for medical device products, in § 861.26 of this chapter.

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

3. In part 809:

a. In § 809.3, by revising paragraph (a) and revoking and reserving paragraph (c) as follows:

§ 809.3 Definitions.

(a) "In vitro diagnostic products" are those reagents, instruments and systems intended for use in the diagnosis of disease or other conditions, including the determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation and examination of specimens taken from the human body. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to section 351 of the Public Health Service Act.

* * * * *

(c) [Reserved]

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b. In § 809.4, by revoking paragraph (b), revising the text of paragraph (a) and removing the paragraph designation. As revised § 809.4 reads as follows:

§ 809.4 Confidentiality of submitted information.

Data and information submitted under § 809.10(c) which is shown to fall within the exemption established in § 20.61 of this chapter, shall be treated as confidential by the Food and Drug Administration and any person to whom it is referred. The Commissioner will determine whether information submitted will be treated as confidential in accordance with the provisions of part 20 of this chapter.

§§ 809.30, 809.34, and 809.35 [Revoked]

c. By revoking Subpart D, consisting of §§ 809.30, Procedure for establishing, amending or repealing standards, 809.34, Court appeal, and 809.35, Regulatory action.

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4. By adding new part 861 to read as follows:

PART 861—PROCEDURES FOR STANDARDS DEVELOPMENT

Subpart A—General

Sec.
861.1 Purpose and scope.
861.5 Statement of policy.
861.7 Content of standards.

Subpart B—Procedures for Standards Development and Publication

861.20 Summary of standards process.
861.22 Invitation for a standard.
861.24 Existing standard as a proposed standard.
861.26 Offer to develop a proposed standard.
861.28 Acceptance of offer to develop a standard.
861.30 Development of standards.
861.32 Contribution by the Commissioner to the costs of developing a proposed standard.
861.34 Amendment or revocation of a standard.
861.36 Effective dates.
861.38 Standards advisory committees.

AUTHORITY: Secs. 501, 502, 513, 514, 701, 52 Stat. 1049-1051 as amended, 1055-1056 as amended, 90 Stat. 540-552 (21 U.S.C. 351, 352, 360c, 360d, 371).

Subpart A—General

§ 861.1 Purpose and scope.

(a) This part implements section 514 of the act with respect to the initiation, development, establishment, amendment, and revocation of performance standards applicable to devices intended for human use.

(b) Performance standards may be established for (1) class II devices, (2) class III devices which, upon the effective date of the standard, are reclassified into class II, and (3) class III devices, as a condition to premarket approval under section 515 of the act in order to reduce or eliminate a risk or risks associated with such device.

§ 861.5 Statement of policy.

In carrying out his duties under this section, the Commissioner 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 participation, through conferences, workshops, or other means, by representatives of scientific, professional, industry, or consumer organizations who can make a significant contribution.

§ 861.7 Contents of standards.

Performance standards established under this part shall include such provisions as the Commissioner determines are necessary to provide reasonable assurance of the safety and effectiveness of the devices for which they are established. Where necessary to provide such assurance, a standard shall include (but is not limited to):

(a) Provisions establishing performance criteria for the device;

(b) Provisions concerning the design, construction, components, ingredients, and properties of the device, and its compatibility with power systems and connections to such systems;

(c) Provisions regarding the manufacturing processes and quality control procedures applicable to the device;

(d) Provisions requiring testing of the device on either a sample or a 100-percent basis by the manufacturer, the Commissioner, and/or a third person to assure that the device conforms to the standard;

(e) Provisions requiring that the results of each test or of certain tests of the device show that the device conforms to the portions of the standard for which the test or tests were required;

(f) Provisions requiring that manufacturers certify to purchasers and/or to the Commissioner that the device conforms to the applicable performance standard;

(g) A provision requiring that the sale and distribution of the device be restricted in accordance with section 520(e) of the act;

(h) Provisions requiring the use, and prescribing the form and content, of labeling for the proper installation, maintenance, operation, and use of the device. Such provisions may include warnings; storage and transportation information; expiration dates; the date and place of manufacture; the results which may be expected if the device is used properly; the ranges of accuracy of diagnosis; instructions regarding the proper care of, and the proper components, accessories, or other equipment to be used with, the device; and statements that the device is considered safe and effective only when used by, or in the treatment of, a patient who has been tested by particular designated procedures by a person skilled in the procedure and found to have an illness or condition for which the device is indicated.

Subpart B—Procedures for Standards Development and Publication

§ 861.20 Summary of standards process.

The procedure by which a performance standard for a device may be developed and promulgated is as follows:

(a) The Commissioner shall initiate a proceeding for the development of a performance standard for a device by publishing in the FEDERAL REGISTER a notice of opportunity to request reclassification of the device (within 15 days of the date of publication of the notice) in accordance with § 860.130 of this part (proposed in the FEDERAL REGISTER of September 13, 1977 (42 FR 46028)).

(b) If, after publication of a notice under paragraph (a), the Commissioner receives a request to change the classification of the device, the Commissioner shall, within 60 days of the publication of the notice, by order published in the FEDERAL REGISTER, either deny the request or give notice of his intent to initiate a change in the classification.

(c) If the Commissioner determines that the device will remain in class II, the Commissioner shall publish in the FEDERAL REGISTER a notice in accordance with § 861.22 inviting any person, including any Federal agency, to submit within 60 days after the date of publication, either an existing standard as a proposed performance standard in accordance with § 861.24, or an offer to develop such a standard in accordance with § 861.26.

(d) Following publication of the invitation for submission of standards in accordance with paragraph (c) of this section and the expiration of the 60-day period provided therein, the Commissioner shall:

(1) If the Commissioner determines that a performance standard can be developed by a Federal agency, based on the personnel, expertise, and resources of the agency, authorize the agency to develop a proposed performance standard or, if the Commissioner determines that an agency within the Department can develop such a standard, have that agency develop a proposed performance standard; or

(2) Accept as a proposed performance standard or as a basis upon which such a standard may be developed, an existing standard submitted in response to the invitation for standards or a standard that has been issued or adopted (or is being developed) by any Federal agency or any other qualified entity if the Commissioner has determined that such standard is based upon scientific data and information and has been subjected to adequate scientific consideration; or

(3) If the Commissioner has neither authorized development of a standard by a Federal agency nor accepted an existing standard in accordance with paragraphs (d) (1) and (2) of this section, accept one or more offers to develop a proposed standard submitted in accordance with § 861.26 and acceptable under § 861.28; or

(4) If neither an offer to develop a standard or an existing standard is submitted or, if submitted, none is accepted or, if accepted, the Commissioner determines that the offeror is unwilling or unable to continue to develop the performance standard or that the performance standard developed is unsatisfactory, proceed to develop a proposed standard in accordance with § 861.30(a); or

(5) Take other appropriate action to facilitate development of a performance standard for the device.

(e) After publication of a notice inviting the submission of an existing standard as a proposed performance standard or an offer to develop such a standard in accordance with § 861.20, the Commissioner may either:

(1) Publish in the FEDERAL REGISTER, in a notice of proposed rulemaking in accordance with § 10.40 of this chapter, a proposed performance standard for the device obtained in accordance with paragraph (c) of this section (the notice of proposed rulemaking shall include proposed findings with respect to the degree of risk of illness or injury the proposed standard is designed to eliminate or reduce and the benefit to the public from the device); or

(2) Terminate the proceeding to develop and promulgate a performance standard by publishing in the FEDERAL REGISTER a notice to that effect, together with the reasons therefor and, unless such notice is issued because the device is a banned device under section 516 of the act, initiate a proceeding under section 513(e) of the act to reclassify the device; or

(3) Take other appropriate action.

(f) If the Commissioner initiates a rulemaking proceeding under paragraph (e)(1) of this section, the commissioner shall, after the expiration of the period for comment and after considering any comments received:

(1) Complete the proceeding and establish the performance standard for the device in accordance with this part and § 10.40 of this chapter; or

(2) Terminate the proceeding by publishing in the FEDERAL REGISTER a notice announcing such termination and the reasons therefor and, unless the proceeding is terminated because the device is a banned device, initiate a proceeding in accordance with section 513(e) of the act to reclassify the device; or

(3) Take other appropriate action.

§ 861.22 Invitation for a standard.

The notice to be published in the FEDERAL REGISTER in accordance with § 861.20(c) inviting offers to develop a performance standard shall contain the following information:

(a) The time period within which the standard is to be developed; this period may be extended by the Commissioner for good cause;

(b) A description or other designation of the device for which a performance standard may be established;

(c) A statement of the risks associated with use of the device and which are intended to be controlled by a performance standard, including pertinent portions of panel classification recommendations with respect to the device;

(d) A summary of the data from which the Commissioner has determined a need for initiation of the proceeding to develop a performance standard, including pertinent portions of the recommendations of classification panels with respect to the device;

(e) Identification of any existing performance standard known to the Commissioner which may be relevant to the proceeding; and

(f) The approximate number of products within the generic type of device which may be subject to the performance standand.

§ 861.24 Existing standard as a proposed standard.

As provided in § 861.20(d)(2), the Commissioner may accept as a proposed standard or as a basis upon which a proposed standard may be developed, an existing standard or a standard that has been issued or adopted (or is being developed), if the Commissioner determines that such standard is based upon scientific data and information and has been subjected to adequate scientific consideration.

(a) Existing standards submitted under this section shall include:

(1) A description of the procedures used to develop the standard and a list of the persons and organizations that participated in its development to the extent that such information is available;

(2) An identification of the specific portions of the existing standard that the person submitting the standard believes are appropriate for adoption as, or inclusion in, the proposed standard; and

(3) A summary of the test data, or, if requested by the Commissioner, all such data or other information supporting the specific portions of the standard identified by the person submitting the standard in accordance with paragraph (a)(2) of this section.

(b) The Commissioner shall publish a notice in the FEDERAL REGISTER stating either that the Commissioner has

accepted as a proposed standard an existing standard or one that has been issued or adopted (or is being developed), or that an existing standard is not acceptable, together with the reasons therefor.

§ 861.26 Offer to develop a proposed standard.

(a) As provided in § 861.20(d)(3), the Commissioner may accept one or more offers to develop a proposed standard. Such offers shall include:

(1) Information on the offeror's expertise and experience that qualifies the offeror to develop a proposed standard for the particular device;

(2) Sufficient information on the offeror's financial stability to establish capability to conduct adequate standards development either with or without contribution by the Commissioner to the offeror's costs;

(3) Information relating to any potential conflicts of interest with respect to development of the standard on the part of the offeror, its directors or officers, or any employees or consultants who may participate in the development of the standard, including any financial interest in the particular device or in the device industry generally, current industrial or commercial affiliates of the offeror, current sources of financial support for research, and all business entities in which the offeror has a financial interest;

(4) Information regarding the offeror's compliance with Federal, State, and local environmental regulations;

(5) A detailed description of the procedures the offeror intends to utilize in developing the standard;

(6) A description of how the offeror intends to provide interested persons adequate and reasonable notice of their right and opportunity to participate in the development of the standard;

(7) A description of the method whereby interested persons who respond to the notice may participate, either in person or through correspondence, in the development of the standard;

(8) A statement describing the facilities or equipment the offeror intends to utilize in developing the standard, and how the offeror intends to gain access to them;

(9) A realistic estimate of the time required to develop the standard, including a detailed schedule for each phase of the procedure;

(10) A description of the method the offeror intends to use to acquire test data or other information needed to support the standard;

(11) A description of the method the offeror intends to use to maintain records of the development of the standard and other relevant matters and to make such records available for disclosure during development, and a schedule of periodic reporting requirements;

(12) If the offeror desires, a request for contribution by the Commissioner to the offeror's cost of developing the standard, which shall include:

(i) A list of the items of expense for which contribution is sought and the amount requested for each item;

(ii) A justification of each item of expense, including and explanation of how the contribution is likely to insure development of a more satisfactory standard;

(iii) A statement that the offeror will employ an adequate accounting system (one in accordance with generally accepted accounting principles) to record standard development costs and expenditures; and

(iv) A statement requesting an advance payment of funds, if necessary to enable the offeror to meet operating expenses during the development period.

(b) Information included in an offer to develop a proposed standard is to be made available to the public only if the offer is accepted, or if required under the provisions of part 20 of this chapter.

§ 861.28 Acceptance to offer to develop a standard.

(a) In determining whether to accept an offer to develop a performance standard under § 861.20(d)(3), the Commissioner shall evaluate the qualifications of the offeror on the basis of the offeror's financial stability, expertise, experience, and potential conflicts of interest. In choosing among competing offerors, the Commissioner shall prefer offerors with no financial interest in the particular device for which a proposed standard is sought or in the device industry generally.

(b) If the conditions provided in § 861.20(d)(3) have been met, and one or more offers that satisfy the requirements of § 861.26 have been submitted, the Commissioner shall accept one, and may accept more than one, offer to develop a proposed standard after determining that:

(1) The offeror is qualified and technically competent to undertake and complete the development of an appropriate standard within the time specified by the Commissioner; and

(2) The offeror will comply with the requirements of § 861.30 in developing the standard.

(c) The Commissioner shall publish in the FEDERAL REGISTER the name and address of each person whose offer to develop a standard is accepted and a summary of the terms of the accepted offer, including a statement of the extent to which the Commissioner will contribute, if at all, to the cost of developing the proposed standard in accordance with § 861.32.

(d) If the Commissioner does not accept an offer to develop a proposed standard submitted in response to an invitation published in accordance with § 861.20, he shall publish in the FEDERAL REGISTER a notice of that fact together with the reasons for his decision.

§ 861.30 Development of standards.

(a) Any person, including the Commissioner and any Federal agency, engaged in the development of a proposed standard under this section shall:

(1) Support its proposed performance standard by such test data or other documents or materials as the Commissioner may reasonably require;

(2) Provide interested persons an opportunity to participate in the development of the standard by accepting comments and, where appropriate, holding public meetings on issues relating to development of the standard. Notice of the opportunity to participate in the development of the standard shall be furnished in a manner reasonably calculated to reach a substantial portion of interested persons. This requirement shall be satisfied by the Commissioner or any Federal agency by publishing such a notice in the FEDERAL REGISTER;

(3) Maintain records disclosing the course of development of the proposed standard, the comments and other information submitted by any person in connection with such development (including comments and information regarding the need for a standard), and such other information as may be required by the Commissioner to evaluate the standard.

(b) Persons engaged in the development of a standard under this section under the terms of an offer accepted by the Commissioner in accordance with § 861.28 shall, in addition to complying with paragraph (a) of this section:

(1) Submit progress reports on a monthly basis or as otherwise required by the Commissioner;

(2) Cooperate fully with the Commissioner and permit duly authorized representatives of the Commissioner to inspect their facilities and developmental activities to determine whether satisfactory progress is being made toward completion of the standard in accordance with paragraph (c) of this section.

(3) Developers receiving contributions from the Commissioner toward the cost of developing the proposed standard in accordance with § 861.32 shall:

(i) Submit to the Commissioner a full accounting of such contributions;

(ii) Remit all unexpended amounts to the Commissioner within 60 calendar days after submission of the standard;

(iii) Maintain, for a period of 3 years after submission of the proposed standard, records that fully disclose the total costs and expenditures for the development of the standard and such other records as are necessary to permit an effective audit;

(iv) Grant to the Commissioner and the Comptroller General of the United States, or any of their duly authorized representatives, access, for the purpose of audit and examination, to any books, documents, papers, and other records relating to the expenditure of any funds contributed by the Commissioner.

(c) Persons engaged in the development of a performance standard under this section under the terms of an offer accepted by the Commissioner in accordance with § 861.26 shall be considered to be making satisfactory progress toward development of the standard if the Commissioner concludes that the developer can develop an adequate proposed standard in accordance with the terms of the accepted offer within the designated time period. If it appears to the Commissioner that such person is not making satisfactory progress, that person will be afforded an opportunity either to demonstrate ability and willingness to complete the development of the standard within the designated time period or to justify the need for an extension of the development period. After evaluating the information available to the Commissioner to determine whether the person is able and willing to complete development of an adequate proposed standard within the designated time period, the Commissioner shall either terminate the person's role in the development process or extend the period for development of the proposed standard. The Commissioner shall require all persons whose role in the development process is terminated to submit all information, records, and documents in their possession which relate to the development of the proposed standard, and to remit all funds contributed by the Commissioner which have not been expended. The Commissioner shall publish in the FEDERAL REGISTER notice of the Commissioner's determination to terminate the role of any person in the development of a proposed standard, together with the reasons for the Commissioner's action. The Commissioner shall periodically evaluate performance standards to determine whether they should be changed to reflect new medical, scientific, or other technological data.

§ 861.32 Contribution by the Commissioner to the costs of developing a proposed standard.

(a) If the Commissioner accepts an offer to develop a proposed standard, the Commissioner may agree to contribute to the costs of developing the standard if the Commissioner determines that such contribution is likely to result in the development of a more satisfactory standard.

(b) The items of cost toward which the Commissioner may contribute are those allowable direct and indirect costs allocable to the development project as set forth in the applicable subparts of 41 CFR Part 1-15 of the Federal procurement regulations. Typical standards development activities to which the Commissioner may contribute include:

(1) Research and analysis of the existing literature pertaining to the medical device that is the subject of the development effort;

(2) Testing of representative medical devices in support of the development effort;

(3) Preparation of and participation in public review of draft standards.

(c) The items of cost to which the Commissioner may not contribute include:

(1) Costs for the construction or acquisition of any interest in land or buildings;

(2) Costs for the payment of salaries in excess of the amount paid by the offeror at the time immediately preceding the offer, excluding routine increases which may accrue during the development period;

(3) Costs for the payment of items in excess of the offeror's actual cost;

(4) Costs for items with a usable lifespan extending beyond the development period, except that contribution may be made toward the portion of the item's cost allocable to the development of the proposed standard as detemined by the difference between the item's estimated market value at the termination of the development period and the total cost of its acquisition; and

(5) Costs determined not to be allowable under generally accepted accounting principles and practices or 41 CFR Part 1-15 of the Federal procurement regulations.

§ 861.34 Amendment or revocation of a standard.

(a) The Commissioner shall provide for periodic evaluation of performance standards to determine whether such standards should be changed to reflect new medical, scientific, or other technological data.

(b) The Commissioner may, on the Commissioner's initiative or upon petition of an interested party, amend or revoke by regulation a standard established under this part.

(c) Petitions to amend or revoke a standard shall:

(1) Identify the specific device and standard for which the amendment or revocation is sought;

(2) Be submitted in accordance with the requirements of § 10.30 of this chapter.

(d) Proceedings to amend or revoke a performance standard shall be conducted in accordance with the rulemaking procedures of § 10.40 of this chapter and are subject to the requirements of § 861.38 with respect to referral to standards advisory committees and § 861.36 with respect to effective dates. In addition, a notice of proposed rule-making to amend or revoke a standard shall set forth proposed findings with respect to the degree of risk or illness to be eliminated or reduced and the benefit the public will derive from the proposed amendment or revocation.

§ 861.36 Effective dates.

(a) A regulation establishing, amending, or revoking a performance standard shall set forth the date upon which it shall take effect. To the extent practicable, consistent with the public health and safety, such effective date shall be established so as to minimize economic loss to, and disruption or dislocation of, domestic and international trade.

(b) Except as provided in paragraph (c) of this section, no regulation establishing, amending, or revoking a standard may take effect before 1 year after the date of its publication unless: (1) The Commissioner determines that an earlier effective date is necessary to protect the public health and safety; or (2) the standard has been established for a device that, by the effective date of the standard, has been reclassified from class III to class II.

(c) The Commissioner may declare a proposed regulation amending a standard effective during the period beginning immediately upon its publication in the FEDERAL REGISTER and until the effective date of any final action on the proposal if the Commissioner determines, after affording interested persons an opportunity for an informal hearing conducted in accordance with part 16 of this chapter, that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device that conforms to the standard without the change or changes provided in the proposed amendment.

§ 861.38 Standards advisory committees.

(a) The Commissioner shall establish advisory committees to which proposed regulations may be referred and these committees shall consider such referrals in accordance with this section and part 14 of this chapter. Such advisory committees, which may not be classification panels, shall be considered ad hoc advisory committees. Their members shall be selected in accordance with §§ 14.82 and 14.84 of this chapter, except that no member may be in the regular full-time employ of the United States and engaged in the administration of the act. Each advisory committee established under this section shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry.

(b) A proposed regulation to establish, amend, or revoke a performance standard shall be referred to an advisory committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment:

(1) On the initiative of the Commissioner, if the Commissioner determines that such referral is necessary or appropriate under the circumstances; or

(2) Upon the request of an interested person in the form of a citizen petition in accordance with § 10.30 of this chapter if submitted within the period provided for comment on the proposed regulation and not determined by the Commissioner to be without good cause or on a matter not involving scientific judgment.

(c) When a proposed regulation is referred to an advisory committee, the Commissioner shall furnish the committee with the data and information upon which the proposed regulation is based. After independently reviewing the materials furnished by the Commissioner and any other available data and information, the advisory committee shall, within 60 days of the referral, submit to the Commissioner a report and recommendation on the proposed regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of the report and recommendation shall be publicly displayed in the office of the Hearing Clerk.

(d) Each proposed regulation establishing a standard published in the FEDERAL REGISTER shall include a call for nominations to the advisory committee for that particular standard.

Interested persons may, on or before September 25, 1978, submit to the Hearing Clerk (HFA-305), Room 4-65, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

The Food and Drug Administration has determined that this proposal will not have a major economic impact as defined by Executive Order 11821 (amended by Executive Order 11949) and OMB Circular A-107. A copy of the economic impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Dated: July 17, 1978.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

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