§ 861.38 Standards advisory committees.

(a) The Food and Drug Administration will 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, except that no member may be a regular full-time FDA employee. 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 if:

(1) The Food and Drug Administration determines that such referral is necessary or appropriate under the circumstances; or

(2) Requested by an interested person, in the form of a citizen petition in accordance with §10.30 of this chapter, which is made within the period provided for comment on the proposed regulation and which demonstrates good cause for referral.

(c) When a proposed regulation is referred to an advisory committee, the Food and Drug Administration will furnish the committee with the data and information upon which the proposed regulation is based. After independently reviewing the materials furnished by the Food and Drug Administration and any other available data and information, the advisory committee shall, within 60 days of the referral, submit 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 will be publicly displayed in the office of the Division of Dockets Management, Food and Drug Administration.

(d) Where appropriate, each proposed regulation establishing a standard published in the Federal Register will include a call for nominations to the advisory committee for that particular standard.

§ 861.39 Definitions.

The following terms have the meanings given them unless other meanings are given in the context:

(1) Device: A device as defined in §860.2(t) of this subchapter.

(2) Performance standard: A product specification which reflects a recognition of the inherent limitations of the testing methods that may be used to measure the safety or effectiveness of a device.

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

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Subpart B—Clinical Chemistry Test Systems

862.1020 Acid phosphatase (total or prostatic) test system.
862.1025 Adrenocorticotropic hormone (ACTH) test system.
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862.1050 Alkaline phosphatase or isoenzymes test system.
862.1055 Newborn screening test system for amino acids, free carnitine, and acylcarnitines using tandem mass spectrometry.
862.1060 Delta-aminolevulinic acid test system.
862.1065 Ammonia test system.
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862.1075 Androstenedione test system.