

Food and Drug Administration, HHS

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found to be equivalent. The provisions of §§ 26.40, 26.41, 26.42, 26.43, 26.44, 26.45, and 26.46 will apply only with regard to listed CAB's and only to the extent of any specifications and limitations contained on the list with regard to a CAB.

(b) The operational period will apply to quality system evaluation reports and product evaluation reports generated by CAB's listed in accordance with this subpart for the evaluations performed in the respective territories of the parties, except if the parties agree otherwise.

§ 26.41 Exchange and endorsement of quality system evaluation reports.

(a) Listed European Community (EC) conformity assessment bodies (CAB's) will provide FDA with reports of quality system evaluations, as follows:

(1) For preapproval quality system evaluations, EC CAB's will provide full reports; and

(2) For surveillance quality system evaluations, EC CAB's will provide abbreviated reports.

(b) Listed U.S. CAB's will provide to the EC Notified Body of the manufacturer's choice:

(1) Full reports of initial quality system evaluations;

(2) Abbreviated reports of quality systems surveillance audits.

(c) If the abbreviated reports do not provide sufficient information, the importing party may request additional clarification from the CAB.

(d) Based on the determination of equivalence in light of the experience gained, the quality system evaluation reports prepared by the CAB's listed as equivalent will normally be endorsed by the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in a report, quality defects identified in postmarket surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the importing party may request clarification from the exporting party which may lead to a request for reinspection. The parties will endeavor to respond to requests for clarification in a timely manner.

Where divergence is not clarified in this process, the importing party may carry out the quality system evaluation.

§ 26.42 Exchange and endorsement of product evaluation reports.

(a) European Community (EC) conformity assessment bodies (CAB's) listed for this purpose will, subject to the specifications and limitations on the list, provide to FDA 510(k) premarket notification assessment reports prepared to U.S. medical device requirements.

(b) U.S. CAB's will, subject to the specifications and limitations on the list, provide to the EC Notified Body of the manufacturer's choice, type examination, and verification reports prepared to EC medical device requirements.

(c) Based on the determination of equivalence in light of the experience gained, the product evaluation reports prepared by the CAB's listed as equivalent will normally be endorsed by the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies, inadequacies, or incompleteness in a product evaluation report, or other specific evidence of serious concern in relation to product safety, performance, or quality. In such cases, the importing party may request clarification from the exporting party which may lead to a request for a reevaluation. The parties will endeavor to respond to requests for clarification in a timely manner. Endorsement remains the responsibility of the importing party.

§ 26.43 Transmission of quality system evaluation reports.

Quality system evaluation reports covered by § 26.41 concerning products covered by this subpart shall be transmitted to the importing party within 60-calendar days of a request by the importing party. Should a new inspection be requested, the time period shall be extended by an additional 30-calendar days. A party may request a new inspection, for cause, identified to the other party. If the exporting party cannot perform an inspection within a specified period of time, the importing

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party may perform an inspection on its own.

§ 26.44 Transmission of product evaluation reports.

Transmission of product evaluation reports will take place according to the importing party's specified procedures.

§ 26.45 Monitoring continued equivalence.

Monitoring activities will be carried out in accordance with § 26.69.

§ 26.46 Listing of additional CAB's.

(a) During the operational period, additional conformity assessment bodies (CAB's) will be considered for equivalence using the procedures and criteria described in §§ 26.36, 26.37, and 26.39, taking into account the level of confidence gained in the overall regulatory system of the other party.

(b) Once a designating authority considers that such CAB's, having undergone the procedures of §§ 26.36, 26.37, and 26.39, may be determined to be equivalent, it will then designate those bodies on an annual basis. Such procedures satisfy the procedures of § 26.66(a) and (b).

(c) Following such annual designations, the procedures for confirmation of CAB's under § 26.66(c) and (d) shall apply.

§ 26.47 Role and composition of the Joint Sectoral Committee.

(a) The Joint Sectoral Committee for this subpart is set up to monitor the activities under both the transitional and operational phases of this subpart.

(b) The Joint Sectoral Committee will be cochaired by a representative of the Food and Drug Administration (FDA) for the United States and a representative of the European Community (EC) who will each have one vote. Decisions will be taken by unanimous consent.

(c) The Joint Sectoral Committee's functions will include:

(1) Making a joint assessment of the equivalence of conformity assessment bodies (CAB's);

(2) Developing and maintaining the list of equivalent CAB's, including any limitation in terms of their scope of activities and communicating the list

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to all authorities and the Joint Committee described in subpart C of this part;

(3) Providing a forum to discuss issues relating to this subpart, including concerns that a CAB may no longer be equivalent and opportunity to review product coverage; and

(4) Consideration of the issue of suspension.

§ 26.48 Harmonization.

During both the transitional and operational phases of this subpart, both parties intend to continue to participate in the activities of the Global Harmonization Task Force (GHTF) and utilize the results of those activities to the extent possible. Such participation involves developing and reviewing documents developed by the GHTF and jointly determining whether they are applicable to the implementation of this subpart.

§ 26.49 Regulatory cooperation.

(a) The parties and authorities shall inform and consult with one another, as permitted by law, of proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

(b) The parties shall notify each other in writing of any changes to Appendix A of this subpart.

§ 26.50 Alert system and exchange of postmarket vigilance reports.

(a) An alert system will be set up during the transition period and maintained thereafter by which the parties will notify each other when there is an immediate danger to public health. Elements of such a system will be described in an Appendix F of this subpart. As part of that system, each party shall notify the other party of any confirmed problem reports, corrective actions, or recalls. These reports are regarded as part of ongoing investigations.

(b) Contact points will be agreed between both parties to permit authorities to be made aware with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which