

APPENDIX E TO SUBPART A OF PART 26—
ELEMENTS TO BE CONSIDERED IN DE-
VELOPING A TWO-WAY ALERT SYS-
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1. Documentation

- Definition of a crisis/emergency and under what circumstances an alert is required
- Standard Operating Procedures (SOP's)
- Mechanism of health hazards evaluation and classification
- Language of communication and transmission of information

2. Crisis Management System

- Crisis analysis and communication mechanisms
- Establishment of contact points
- Reporting mechanisms

3. Enforcement Procedures

- Followup mechanisms
- Corrective action procedures

4. Quality Assurance System

- Pharmacovigilance programme
- Surveillance/monitoring of implementation of corrective action

5. Contact Points

For the purpose of subpart A of this part, the contact points for the alert system will be:

A. For the European Community:

the Executive Director of the European Agency for the Evaluation of Medicinal Products, 7, Westferry Circus, Canary Wharf, UK - London E14 4HB, England. Telephone 44-171-418 8400, Fax 418-8416.

B. For the United States :

Biologics: Director, Office of Compliance and Biologics Quality (HFM-600), 1401 Rockville Pike, Rockville, MD 20852, phone: 301-827-6190, fax: 301-594-1944.

Human Drugs: Director, Office of Compliance (HFD-300), MPN I, 7520 Standish Pl., Rockville, MD 20855-2737, phone: 301-594-0054, fax: 301-594-2114.

Veterinary Drugs: Director, Office of Surveillance and Compliance (HFV-200), MPN II, 7500 Standish Pl., Rockville, MD 20855-2773, phone: 301-827-6644, fax: 301-594-1807.

Subpart B—Specific Sector Provisions for Medical Devices

§ 26.31 Purpose.

(a) The purpose of this subpart is to specify the conditions under which a party will accept the results of quality system-related evaluations and inspections and premarket evaluations of the

other party with regard to medical devices as conducted by listed conformity assessment bodies (CAB's) and to provide for other related cooperative activities.

(b) This subpart is intended to evolve as programs and policies of the parties evolve. The parties will review this subpart periodically, in order to assess progress and identify potential enhancements to this subpart as Food and Drug Administration (FDA) and European Community (EC) policies evolve over time.

§ 26.32 Scope.

(a) The provisions of this subpart shall apply to the exchange and, where appropriate, endorsement of the following types of reports from conformity assessment bodies (CAB's) assessed to be equivalent:

(1) Under the U.S. system, surveillance/postmarket and initial/preapproval inspection reports;

(2) Under the U.S. system, premarket (510(k)) product evaluation reports;

(3) Under the European Community (EC) system, quality system evaluation reports; and

(4) Under the EC system, EC type examination and verification reports.

(b) Appendix A of this subpart names the legislation, regulations, and related procedures under which:

(1) Products are regulated as medical devices by each party;

(2) CAB's are designated and confirmed; and

(3) These reports are prepared.

(c) For purposes of this subpart, equivalence means that: CAB's in the EC are capable of conducting product and quality systems evaluations against U.S. regulatory requirements in a manner equivalent to those conducted by FDA; and CAB's in the United States are capable of conducting product and quality systems evaluations against EC regulatory requirements in a manner equivalent to those conducted by EC CAB's.

§ 26.33 Product coverage.

(a) There are three components to this subpart each covering a discrete range of products:

(1) *Quality System Evaluations.* U.S.-type surveillance/postmarket and initial/preapproval inspection reports and European Community (EC)-type quality system evaluation reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(2) *Product Evaluation.* U.S.-type premarket (510(k)) product evaluation reports and EC-type-testing reports will be exchanged only with regard to those products classified under the U.S. system as Class I/Class II-Tier 2 medical devices which are listed in Appendix B of this subpart.

(3) *Postmarket Vigilance Reports.* Postmarket vigilance reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(b) Additional products and procedures may be made subject to this subpart by agreement of the parties.

§ 26.34 Regulatory authorities.

The regulatory authorities shall have the responsibility of implementing the provisions of this subpart, including the designation and monitoring of conformity assessment bodies (CAB's). Regulatory authorities will be specified in Appendix C of this subpart. Each party will promptly notify the other party in writing of any change in the regulatory authority for a country.

§ 26.35 Length and purpose of transition period.

There will be a 3-year transition period immediately following the date described in § 26.80(a). During the transition period, the parties will engage in confidence-building activities for the purpose of obtaining sufficient evidence to make determinations concerning the equivalence of conformity assessment bodies (CAB's) of the other party with respect to the ability to perform quality system and product evaluations or other reviews resulting in reports to be exchanged under this subpart.

§ 26.36 Listing of CAB's.

Each party shall designate conformity assessment bodies (CAB's) to participate in confidence building activities by transmitting to the other

party a list of CAB's which meet the criteria for technical competence and independence, as identified in Appendix A of this subpart. The list shall be accompanied by supporting evidence. Designated CAB's will be listed in Appendix D of this subpart for participation in the confidence building activities once confirmed by the importing party. Nonconfirmation would have to be justified based on documented evidence.

§ 26.37 Confidence building activities.

(a) At the beginning of the transitional period, the Joint Sectoral Group will establish a joint confidence building program calculated to provide sufficient evidence of the capabilities of the designated conformity assessment bodies (CAB's) to perform quality system or product evaluations to the specifications of the parties.

(b) The joint confidence building program should include the following actions and activities:

(1) Seminars designed to inform the parties and CAB's about each party's regulatory system, procedures, and requirements;

(2) Workshops designed to provide the parties with information regarding requirements and procedures for the designation and surveillance of CAB's;

(3) Exchange of information about reports prepared during the transition period;

(4) Joint training exercises; and

(5) Observed inspections.

(c) During the transition period, any significant problem that is identified with a CAB may be the subject of cooperative activities, as resources allow and as agreed to by the regulatory authorities, aimed at resolving the problem.

(d) Both parties will exercise good faith efforts to complete the confidence building activities as expeditiously as possible to the extent that the resources of the parties allow.

(e) Both the parties will each prepare annual progress reports which will describe the confidence building activities undertaken during each year of the transition period. The form and content of the reports will be determined by the parties through the Joint Sectoral Committee.