APPENDIX E TO SUBPART A OF PART 26—ELEMENTS TO BE CONSIDERED IN DEVELOPING A TWO-WAY ALERT SYSTEM

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:
   B. For the United States:


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.