§ 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 could necessitate additional controls or suspension of the distribution of the product.

APPENDIX A TO SUBPART B OF PART 26—RELEVANT LEGISLATION, REGULATIONS, AND PROCEDURES.

1. For the European Community (EC) the following legislation applies to §26.42(a) of this subpart:


2. For the United States, the following legislation applies to §26.32(a):

   b. The Public Health Service Act, 42 U.S.C. 201 et seq.
   c. Regulations of the United States Food and Drug Administration found at 21 CFR, in particular, Parts 800 to 1299.

APPENDIX B TO SUBPART B OF PART 26—SCOPE OF PRODUCT COVERAGE

1. Initial Coverage of the Transition Period

   Upon entry into force of this subpart as described in §25.80 (it is understood that the date of entry into force will not occur prior to June 1, 1998, unless the parties decide otherwise), products qualifying for the transitional arrangements under this subpart include:

   a. All Class I products requiring premarket evaluations in the United States—see Table 1.
   b. Those Class II products listed in Table 2.

2. During the Transition Period

   The parties will jointly identify additional product groups, including their related accessories, in line with their respective priorities as follows:

   a. Those for which review may be based primarily on written guidance which the parties will use their best efforts to prepare expeditiously; and