Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 of FAA Order 7400.9E, *Airspace Designations and Reporting Points*, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1 (62 FR 52491; October 8, 1997). The Class E airspace designation listed in this document would be revised and published subsequently in the Order.

The FAA has determined that these proposed regulations only involve an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71— DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, *Airspace Designations and Reporting Points*, dated September 10, 1997, and effective September 16, 1997, is to be amended as follows:

Paragraph 6005 Class E airspace extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Kotzebue, AK

Kotzebue, Ralph Wien Memorial Airport, AK
(Lat. 66°53′05″ N, long. 162°35′55″ W)
Kotzebue VOR/DME
(Lat. 66°53′08″ N, long. 162°32′24″ W)
Hotham NDB
(Lat. 66°54′05″ N, long. 162°33′52″ W)

That airspace extending upward from 700 feet above the surface within a 6.8 mile radius of the Ralph Wien Memorial Airport and within 14 miles of the Kotzebue VOR/DME extending clockwise from the 206° radial to the 130° radial and within 4 miles southeast and 8 miles northwest of the Hotham NDB 039° bearing extending from the NDB to 16 miles northeast of the NDB and within 4 miles north and 8 miles south of the Kotzebue VOR/DME 278° radial extending from the VOR/DME to 20 miles west of the VOR/DME; and that airspace extending upward from 1,200 feet above the surface within 18 miles of the Kotzebue VOR/DME clockwise from the 020° radial to the 130° radial and within 38 miles of the Kotzebue VOR/DME clockwise from the 130° radial to the 314° radial and within 4.3 miles each side of the Kotzebue VOR/DME 103° radial extending from the VOR/DME to 34 miles east of the VOR/DME; and that airspace extending upward from 5,500 feet MSL within 4.3 miles each side of the Kotzebue VOR/DME 103° radial extending from 34 miles east of the VOR/DME to 51.3 miles east of the VOR/DME; and that airspace extending upward from 7,500 feet MSL within 4.3 miles each side of the Kotzebue VOR/DME 103° radial at 51.3 miles east of the Kotzebue VOR/DME widening to 7.4 miles each side of the 103° radial at 96 miles east of the Kotzebue VOR/DME.

* * * * *

Issued in Anchorage, AK, on April 3, 1998.

Willis C. Nelson,

Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 98–9510 Filed 4–9–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 26

[Docket No. 95N–0185]

RIN 0910–ZA11

Mutual Recognition of the Food and Drug Administration and European Community Member State Conformity Assessment Procedures; Pharmaceutical GMP Inspection Reports, Medical Device Quality System Evaluation Reports, and Certain Medical Device Premarket Evaluation Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations pursuant to an international agreement that is expected to be concluded between the United States and the European Community (EC) (Ref. 1). Under the terms of that agreement, FDA may normally endorse good manufacturing practice (GMP) inspection reports for pharmaceuticals provided by equivalent EC Member State regulatory authorities and medical device quality system evaluation reports and certain medical device premarket evaluation reports provided by equivalent conformity assessment bodies. FDA is taking this action to enhance its ability to ensure the safety and efficacy of pharmaceuticals and medical devices through more efficient and effective utilization of its regulatory resources. The agency is requesting comments on the proposed rule.

DATES: Comments by May 11, 1998. Comments must be received by the Dockets Management Branch (address below) by 4:30 p.m. Eastern Standard Time on May 11, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, fax 301–594–3215.

FOR FURTHER INFORMATION CONTACT: Merton V. Smith, Office of International Affairs (HFG–1), Office of External Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0910, or E-mail: ''MSmith@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background and History

On June 20, 1997, the United States and the EC concluded negotiations of an agreement entitled ''Agreement on Mutual Recognition between the United States of America and the European Community'' (also called ''the MRA''). The MRA includes two sectoral annexes covering products regulated by FDA. The medical device sectoral annex covers medical device quality system-related inspection reports and premarket evaluation reports. The pharmaceutical GMP sectoral annex covers pharmaceutical GMP inspection reports. The MRA also includes sectoral annexes covering products regulated by other U.S. regulatory agencies, including telecommunication equipment, electromagnetic compatibility, electrical safety, and recreational craft. Finally, the MRA includes an ''umbrella'' agreement that contains general provisions applicable

to the operation of all of the sectoral annexes.

At the conclusion of negotiations, the United States and the EC agreed to submit the text of the MRA to their respective authorities to complete the necessary procedures for approval and implementation (Ref. 2). For FDA, the procedures include publishing this proposed rule for public comment.

In this document, FDA has published relevant provisions of the two FDA sectoral annexes and the umbrella agreement, some of which create binding obligations. FDA will review all comments and will consider those comments addressing its binding obligations under the agreement.

II. Statutory Authority

FDA has the authority to enter into and execute the MRA under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*) and the Public Health Service Act (the PHS Act) (42 U.S.C. 201 *et seq.*). For drugs and medical devices, section 510(i)(3) of the act (21 U.S.C. 360(i)(3)) provides authority for FDA to enter into the MRA. Section 510(i)(3) of the act provides that:

> The Secretary [FDA by delegation] is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment * * * [described in this section], if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

(Ref. 3).

The MRA and the pharmaceutical and medical device annexes represent cooperative arrangements with officials from foreign countries. The purpose of these arrangements is, among other things, to ensure FDA has adequate and effective means to determine whether drugs or devices offered for import are adulterated, misbranded, or in violation of section 505 of the act (21 U.S.C. 355) (Ref. 4). FDA's authority to make these determinations is found at section 801(a) of the act (21 U.S.C. 381(a)).

Section 803(b) of the act (21 U.S.C. 383(b)) provides FDA with authority to enter into the medical device sectoral annex. That section authorizes FDA to enter into agreements with foreign countries to facilitate commerce in medical devices, consistent with the provisions of the act. Such agreements are to encourage the mutual recognition of GMP regulations relating to devices, as well as other regulations and testing protocols determined by the Secretary (FDA by delegation) to be appropriate.

Additional support for FDA authority to enter into this MRA is found in the PHS Act. Under section 307 of the PHS Act (42 U.S.C. 242l), the Secretary of Health and Human Services (FDA by delegation) has authority ''to participate with other countries in cooperative endeavors'' in biomedical research and health care technology. In addition, the Secretary of Health and Human Services (FDA by delegation) has authority under section 301 of the PHS Act (42 U.S.C. 241) to ''cooperate with, and render assistance to other appropriate public authorities * * * in the conduct of * * * investigations * * * relating to the * * * prevention of physical and mental diseases and impairments of man * * * .'' The cooperative activities between FDA and the EC set forth in the MRA and this proposed regulation, fall within FDA's delegated authority under these sections of the PHS Act.

Finally, a provision of the recently enacted FDAMA provides authority for FDA to participate in MRA activities. Section 410 of FDAMA authorizes FDA to ''support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, [and] devices * * * and the regulation of good manufacturing practices, between the European Union and the United States'' (Ref. 5). During negotiation of this MRA, officials from FDA, the Office of the United States Trade Representative, and the Department of Commerce participated in activities in an effort to move toward acceptance of a mutual recognition agreement.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (Pub. L. 96–354, as amended by Pub. L. 104–121), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires agencies to prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any one year.

The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order and in these two statutes. Through this regulation, the agency is proposing to set out requirements through which it may normally endorse certain conformity assessment procedure reports. Such reports would be provided by equivalent EC Member State regulatory authorities for manufacturing site inspections to ascertain conformity with pharmaceutical GMP's and by equivalent conformity assessment bodies for quality system audits and certain medical device premarket evaluations. Obtaining conformity assessment information in the manner described in the proposed rule is inherently more efficient and cost-effective than the existing approach, where additional inspection efforts by FDA in foreign countries are necessary because foreign regulatory systems have not been found equivalent. The primary benefit of the proposed rule is to provide credible assurance that the rapidly increasing volume of EC Member States' imports into the United States meet pharmaceutical GMP requirements, and medical device quality system evaluation and certain premarket evaluation requirements, as specified in U.S. statutes and regulations. In the future, this credible assurance must be achievable without resource expenditures by FDA that are directly proportional to the volume of trade.

In recent years, the credibility of the current approach has been strained as FDA's essentially constant foreign inspection capacity has been stretched over an expanding volume of imports from the EC. In the 3-year interval between 1994 and 1997, the value of EC pharmaceutical and medical device imports into the United States has nearly doubled from $5.5 billion to more than $10.7 billion. Growth has been greatest in pharmaceuticals, where

annual EC exports have increased by more than $2 billion in each of the last 2 years. In 1997, FDA conducted one inspection in the EC for every $60 million in pharmaceutical exports to the United States, which is less than half the coverage intensity of 1994. In addition, the majority of these inspections have been preapproval in nature. Continuation of the current trend will further decrease FDA's coverage intensity to less than one inspection per $100 million in EC pharmaceutical exports by the year 2000. Equivalence with EC Member State regulatory systems has the potential for leveraging FDA's regulatory resources so that necessary conformity assessments can be ensured for higher volumes of future trade.

In addition to coping with higher trade volumes, mutual recognition or equivalence-based agreements with exporting nations may permit FDA to redirect some of its inspectional resources to risk priorities not covered by such agreements. This flexibility would provide a more responsive level of U.S. consumer protection in the face of a changing global marketplace with inherently variable risk management priorities.

Another important benefit of the proposed rule would be the cost savings realized by the regulated industry, largely as a result of sharing inspection reports among equivalent regulatory authorities. This exchange, in turn, will eliminate the need for duplicative inspections and permit individual firms to undergo fewer inspections of manufacturing sites. FDA does not have data on the average administrative cost incurred by pharmaceutical (including biological) or medical device manufacturers as they participate in regulatory inspections, but it is reasonable to assume that the avoidance of redundant inspections would generate cost savings. The proposed rule also may shorten product review times for regulated products as a result of the increased efficiency of premarket approval inspection activities and the third-party evaluation of certain medical devices. Quantification of this savings will be highly dependent on the specific countries that achieve equivalence and the number of medical device audits and evaluations performed by conformity assessment bodies.

The costs of this regulation appear to impact more directly on governmental regulatory agencies than on the regulated industry. These governmental costs involve both startup and operational components. FDA has not received additional government funding earmarked for achieving mutual recognition agreements. FDA, therefore, must proceed to implement these agreements as a concurrent function within normal day-to-day regulatory activities. The 3-year transition period reflects the necessity to absorb these startup costs within existing regulatory budgets. Some activities such as joint inspections may be reasonably easy to absorb as concurrent functions that do not require additional funding, while others such as developing and maintaining systems for routine information exchange may involve new activities. These absorbed governmental costs will fall heavily on FDA, as it must assess equivalence of multiple EC Member States and notified bodies.

For FDA, the absorption of these startup costs will be easier with respect to those EC Member States with a large volume of trade, where FDA already conducts enough inspections to gather a general understanding of the requirements and regulatory practices of the exporting country. From this perspective, the pace and priorities for mutual recognition agreements during the transition period may be dictated by FDA's ability to conduct these processes as concurrent functions within current activities.

In the longer run, an operational system of mutual recognition agreements could pose additional costs on regulatory authorities of exporting countries if equivalence requires a frequency, focus or content of inspections not presently included in regulatory requirements of the exporting nation. For example, Country A may not be able to provide the frequency of medical device inspections desired by Country B without conducting inspections beyond those required for Country A's domestic inspection strategy. Conversely, Country B may not be able to provide to Country A adequate details of the quality of pharmaceutical source materials, because Country B does not have inspectional authority over pharmaceutical starting materials. To the extent such costs are insignificant or offset by other savings, they will not likely be obstacles to reaching agreement on equivalence.

This proposal is not expected to involve any new incremental costs to the affected industry. Although joint inspections during the transition period may create the appearance of more regulatory effort, they should not impose additional costs on the firms inspected. FDA does not anticipate an increase in the total number of inspections, and in fact, the coverage intensity of FDA inspections in the EC would continue to fall during the transition period, as it has been for the past several years. Other activities related to equivalence determinations, such as the procedures for exchanging information and reports, focus on the interface and coordination between regulatory agencies and, as such, do not affect industry in a cost context.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities unless the rule is not expected to have a significant impact on a substantial number of small entities. As the proposed regulation is not expected to impose costs on the regulated industry, the agency certifies that the proposed rule would not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The Unfunded Mandates Act of 1995 requires that agencies prepare an assessment of the anticipated costs and benefits before issuing any final rule that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year. This proposed rule does not impose any mandates on State, local or tribal governments, or the private sector that would result in an annual expenditure of $100,000,000 or more. Therefore, no further analysis is appropriate for this requirement.

V. Paperwork Reduction Act of 1995

This proposed rule does not contain any information collection provisions that would be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

VI. Request for Comments

Interested persons may, on or before May 11, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposed regulation. Comments must be received by the Dockets Management Branch by 4:30 p.m. Eastern Standard Time May 11, 1998. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments, a copy of the MRA, and a summary explanation of the MRA's provisions, to aid in commenting, may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. In addition, an electronic copy of the MRA and the summary

explanation is available on FDA's web site at ''http://www.fda.gov'' under the ''international'' heading menu item.

The comment period in this document is shorter than the 60 days FDA customarily provides for proposed rules (21 CFR 10.40(b)(2)). FDA believes it is unnecessary to provide 60 days for comment, given the opportunities for public comment the agency already has provided. During the course of the negotiations of the MRA, FDA provided a number of opportunities for public discussion. For example, on May 9, 1996 (61 FR 21194), FDA established a public docket for information concerning the MRA (Ref. 6). In addition, on October 18, 1996, FDA made available for public comment copies of a document entitled, ''FDA Proposal for an Agreement With the European Union Concerning the Mutual Recognition of Inspections to Determine Adherence to Manufacturing Practices for Pharmaceuticals Including Biologicals.'' FDA formally sought public comment on this proposal through a **Federal Register** notice (61 FR 54448, October 18, 1996). To provide opportunity for public input into the pharmaceutical GMP discussions with the European Commission, FDA hosted public exchange meetings in Washington, DC, and Rockville, MD, on March 31, 1995 (see 60 FR 15934, March 28, 1995), and October 30, 1996 (see 61 FR 54448, October 18, 1996). On November 8 and 9, 1996, a transatlantic business dialogue (TABD) meeting included an extensive discussion of the unresolved issues for the pharmaceutical and medical device annexes to the MRA (Ref. 7), and on March 14, 1997, FDA participated in a meeting of U.S. agencies and nongovernmental organizations, which included several consumer, industry, and environmental groups. Finally, FDA provided information and solicited comment on the MRA at a September 23, 1997, National Consumer Forum held in Washington, DC. The purpose of the forum was to facilitate dialogue on the MRA between FDA and consumers.

In light of the extensive opportunities for public participation, FDA believes there is good cause to provide 30 days for comment on this proposed rule. The agency also believes it is in the public interest to proceed expeditiously to implement the MRA, so that it can proceed toward the anticipated resource efficiencies and enhancement of product safety, effectiveness, and quality that the MRA can provide. The 30-day comment period provides sufficient opportunity to receive and consider comments before the anticipated signing of the MRA in late spring or early summer.

The agency also notes that the comment period is less than that required by Executive Order 12889 (58 FR 69681, December 30, 1993). Section 4 of Executive Order 12889 states that any agency subject to the Administrative Procedure Act shall provide a 75-day comment period for any proposed technical regulation. Because this proposed rule creates no new technical obligations or mandatory requirements on the public, FDA believes that it is not a technical regulation subject to Section 4 of Executive Order 12889. As a result, a 75-day comment period is not required for this proposed rule.

VII. References

1. The European Community consists of the following member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom. These countries have vested in the European Commission the authority to conduct certain international negotiations, on their behalf, with other countries such as the United States.

2. On June 20, 1997, U.S. Trade Representative Charlene Barshefsky and European Commission Vice President Leon Brittan signed ''Agreed Minutes on the Agreement on Mutual Recognition between the United States of America and the European Community,'' which states that the MRA ''represents the text we commit to submit to our respective authorities with a view to completing the necessary procedures for approval and implementation.'' The complete text of the MRA is available on the Internet at FDA's web site, ''http://www.fda.gov'', under the ''international'' menu item or on the European Community web site, ''http://europa.eu.int/en/comm/dg01/mra03.htm''.

3. Food and Drug Administration Modernization Act of 1997 (FDAMA), section 417, Pub. L. 105–115, 111 Stat. 2296 (1997) (to be codified at 21 U.S.C. 360(i)(3)).

4. Provisions in the act that govern FDA regulation of pharmaceuticals and medical devices include sections 501, 502, 505, 512, 513, 520, and 522 (21 U.S.C. 351, 352, 355, 360b, 360c, 360j, and 360l).

5. FDAMA section 410 (to be codified at 21 U.S.C. 383(c)(2)).

6. Information in the docket includes summaries of minutes of the meetings described in this document with written comments received from interested parties, summaries of the various negotiation sessions between FDA and the European Commission and EC Member State representatives, and copies of draft agreements covering pharmaceutical GMP's and medical devices that were exchanged between the EC and FDA in December 1996 and January 1997.

7. The TABD is an industry-driven initiative that aims to facilitate closer economic relations between the EC and the United States.

VIII. Comparison Table

The following table shows the relationship of the MRA Articles and the sections of the Code of Federal Regulations (CFR) as proposed under this rule:

TABLE 1.—RELATIONSHIP OF THE MRA ARTICLES TO SECTIONS IN THE CFR

MRA Article	CFR Section
Sectoral Annex for Pharmaceutical GMP's	Subpart A
Article 1	26.1
Article 2	26.2
Article 3	26.3
Article 4	26.4
Article 5	26.5
Article 6	26.6
Article 7	26.7
Article 8	26.8
Article 9	26.9
Article 10	26.10
Article 11	26.11
Article 12	26.12
Article 13	26.13
Article 14	26.14
Article 15	26.15
Article 16	26.16
Article 17	26.17
Article 18	26.18
Article 19	26.19
Article 20	26.20
Article 21	26.21
Appendix 1	Appendix A
Appendix 2	Appendix B
Appendix 3	Appendix C
Appendix 4	Appendix D
Appendix 5	Appendix E

MRA Article	CFR Section
Sectoral Annex on Medical Devices	Subpart B
Article 1	26.31
Article 2	26.32
Article 3	26.33
Article 4	26.34
Article 5	26.35
Article 6	26.36
Article 7	26.37
Article 8	26.38
Article 9	26.39
Article 10	26.40
Article 11	26.41
Article 12	26.42
Article 13	26.43
Article 14	26.44
Article 15	26.45
Article 16	26.46
Article 17	26.47
Article 18	26.48
Article 19	26.49
Article 20	26.50
Appendix 1	Appendix A

MRA Article	CFR Section
Sectoral Annex on Medical Devices	Subpart B
Appendix 2 and Tables 1–3.	Appendix B and Tables 1–3
Appendix 3 [Reserved].	Appendix C [Reserved]
Appendix 4 [Reserved].	Appendix D [Reserved]
Appendix 5 [Reserved].	Appendix E [Reserved]
Appendix 6 [Reserved].	Appendix F [Reserved]

MRA Article	CFR Section
Umbrella Agreement	Subpart C
Article 1	26.60
Article 2	26.61
Article 3	26.62
Article 4	26.63
Article 5	26.64
Article 6	26.65
Article 7	26.66
Article 8	26.67
Article 9	26.68
Article 10	26.69
Article 11	26.70
Article 12	26.71
Article 13	26.72
Article 14	26.73
Article 15	26.74
Article 16	26.75
Article 17	26.76
Article 18	26.77
Article 19	26.78
Article 20	26.79
Article 21	26.80
Article 22	26.81

List of Subjects in 21 CFR Part 26

Animal and human drugs, Biologicals, Devices, Exports, Imports, Incorporation by reference, and Inspections.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended by adding part 26 to read as follows:

PART 26—MUTUAL RECOGNITION OF PHARMACEUTICAL GOOD MANUFACTURING PRACTICE REPORTS, MEDICAL DEVICE QUALITY SYSTEM AUDIT REPORTS, AND CERTAIN MEDICAL DEVICE PREMARKET EVALUATION REPORTS PROVIDED BY EUROPEAN COMMUNITY MEMBER STATE REGULATORY AUTHORITIES AND EUROPEAN COMMUNITY CONFORMITY ASSESSMENT BODIES

Sec.

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 343, 351, 352, 355, 360, 360b, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, 360l, 371, 374, 381, 382, 383, 393; 42 U.S.C. 216, 241, 242l, 262, 264, 265.

§ 26.0 General.

This part substantially reflects relevant provisions of the proposed international agreement entitled, ''Agreement on Mutual Recognition Between the United States of America and the European Community'' (the MRA), including the ''umbrella'' text and its sectoral annexes on pharmaceutical good manufacturing practices (GMP's) and medical devices. Whereas the parties to the MRA would be the United States and the European Community (EC), this part is relevant only to the Food and Drug Administration's (FDA's) implementation of the MRA and the

sectoral annexes cited in this section. For codification purposes, certain provisions of the MRA have been modified for use in this part. This modification is done for purposes of clarity only and shall not affect the text of the MRA to be concluded between the United States and the EC, or the rights and obligations of the United States or EC under that agreement. References to the terms ''party'' or ''parties'' reflect FDA's proposed implementation of the MRA and its sectoral annexes. It is understood that the EC will also be a party to the MRA and that it will implement the MRA in accordance with its internal procedures. If the parties to the MRA subsequently amend or terminate the MRA, FDA will modify this part accordingly, using appropriate administrative procedures.

Subpart A—Specific Sector Provisions for Pharmaceutical Good Manufacturing Practices

§ 26.1 Definitions.

(a) *Enforcement* means action taken by an authority to protect the public from products of suspect quality, safety, and efficacy or to assure that products are manufactured in compliance with appropriate laws, regulations, standards, and commitments made as part of the approval to market a product.

(b) *Equivalence* of the regulatory systems means that the systems are sufficiently comparable to assure that the process of inspection and the ensuing inspection reports will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. *Equivalence* does not require that the respective regulatory systems have identical procedures.

(c) *Good Manufacturing Practices (GMP's)*: [These GMP conceptual definitions are to be merged by the parties at a future date.]

(1) GMP's mean the requirements found in the respective legislations, regulations, and administrative provisions for methods to be used in, and the facilities or controls to be used for, the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

(2) GMP's are that part of quality assurance which ensures that products are consistently produced and controlled to quality standards. For the purpose of this subpart, GMP's include, therefore, the system whereby the manufacturer receives the specifications of the product and/or process from the marketing authorization/product authorization or license holder or applicant and ensures the product is made in compliance with its specifications (qualified person certification in the European Community (EC)).

(d) *Inspection* means an onsite evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with GMP's and/or commitments made as part of the approval to market a product.

(e) *Inspection Report* means the written observations and GMP's compliance assessment completed by an authority listed in Appendix B of this subpart.

(f) *Regulatory System* means the body of legal requirements for GMP's, inspections, and enforcements that ensure public health protection and legal authority to assure adherence to these requirements.

§ 26.2 Purpose.

The provisions of this subpart govern the exchange between the parties and normal endorsement by the receiving regulatory authority of official good manufacturing practice (GMP) inspection reports after a transitional period aimed at determination of the equivalence of the regulatory systems of the parties, which is the cornerstone of this subpart.

§ 26.3 Scope.

(a) The provisions of this subpart shall apply to pharmaceutical inspections carried out in the United States and Member States of the European Community (EC) before products are marketed (hereafter referred to as ''preapproval inspections'') as well as during their marketing (hereafter referred to as ''postapproval inspections'').

(b) Appendix A of this subpart names the laws, regulations, and administrative provisions governing these inspections and the good manufacturing practice (GMP) requirements.

(c) Appendix B of this subpart lists the authorities participating in activities under this subpart.

(d) Sections 26.65, 26.66, 26.67, 26.68, 26.69, and 26.70 of subpart C of this part do not apply to this subpart.

§ 26.4 Product coverage.

(a) These provisions will apply to medicinal products for human or animal use, intermediates and starting materials (as referred to in the European Community (EC)) and to drugs for human or animal use, biological products for human use, and active pharmaceutical ingredients (as referred to in the United States), only to the extent they are regulated by the authorities of both parties as listed in Appendix B of this subpart.

(b) Human blood, human plasma, human tissues and organs, and veterinary immunologicals (under 9 CFR 101.2, ''veterinary immunologicals'' are referred to as ''veterinary biologicals'') are excluded from the scope of this subpart. Human plasma derivatives (such as immunoglobulins and albumin), investigational medicinal products/new drugs, human radiopharmaceuticals, and medicinal gases are also excluded during the transition phase, their situation will be reconsidered at the end of the transition period. Products regulated by FDA's Center for Biologics Evaluation and Research as devices are not covered under this subpart.

(c) Appendix C of this subpart contains an indicative list of products covered by this subpart.

§ 26.5 Length of transition period.

A 3-year transition period will start immediately after the effective date described in § 26.80(a).

§ 26.6 Equivalence assessment.

(a) The criteria to be used by the parties to assess equivalence are listed in Appendix D of this subpart. Information pertaining to the criteria under European Community (EC) competence will be provided by the EC.

(b) The authorities of the parties will establish and communicate to each other their draft programs for assessing the equivalence of the respective regulatory systems in terms of quality assurance of the products and consumer protection. These programs will be carried out, as deemed necessary by the regulatory authorities, for post- and preapproval inspections and for various product classes or processes.

(c) The equivalence assessment shall include information exchanges (including inspection reports), joint training, and joint inspections for the purpose of assessing regulatory systems and the authorities' capabilities. In conducting the equivalence assessment, the parties will ensure that efforts are made to save resources.

(d) Equivalence assessment for authorities added to Appendix B of this subpart after the effective date of this part as described in § 26.80(a) will be conducted as described in this subpart, as soon as practicable.

§ 26.7 Participation in the equivalence assessment and determination.

The authorities listed in Appendix B of this subpart will actively participate in these programs to build a sufficient body of evidence for their equivalence determination. Both parties will exercise good faith efforts to complete equivalence assessment as expeditiously as possible to the extent the resources of the authorities allow.

§ 26.8 Other transition activities.

As soon as possible, the authorities will jointly determine the essential information which must be present in inspection reports and will cooperate to develop mutually agreed inspection report format(s).

§ 26.9 Equivalence determination.

(a) Equivalence is established by having in place regulatory systems covering the criteria referred to in Appendix D of this subpart, and a demonstrated pattern of consistent performance in accordance with these criteria. A list of authorities determined as equivalent shall be agreed to by the Joint Sectoral Committee at the end of the transition period, with reference to any limitation in terms of inspection type (e.g., postapproval or preapproval) or product classes or processes.

(b) The parties will document insufficient evidence of equivalence, lack of opportunity to assess equivalence or a determination of nonequivalence, in sufficient detail to allow the authority being assessed to know how to attain equivalence.

§ 26.10 Regulatory authorities not listed as currently equivalent.

Authorities not currently listed as equivalent, or not equivalent for certain types of inspections, product classes or processes may apply for reconsideration of their status once the necessary corrective measures have been taken or additional experience is gained.

§ 26.11 Start of operational period.

(a) The operational period shall start at the end of the transition period and its provisions apply to inspection reports generated by authorities listed as equivalent for the inspections performed in their territory.

(b) In addition, when an authority is not listed as equivalent based on adequate experience gained during the transition period, FDA will accept for normal endorsement (as provided in § 26.12) inspection reports generated as a result of inspections conducted jointly by that authority on its territory and another authority listed as equivalent, provided that the authority of the Member State in which the inspection is performed can guarantee enforcement of the findings of the inspection report and require that corrective measures be taken when necessary. FDA has the option to participate in these inspections, and based on experience gained during the transition period, the parties will agree on procedures for exercising this option.

(c) In the European Community (EC), the qualified person will be relieved of responsibility for carrying the controls laid down in Article 22 paragraph 1(b) of Council Directive 75/319/EEC (see Appendix A of this subpart) provided that these controls have been carried out in the United States and that each batch/lot is accompanied by a batch certificate (in accordance with the World Health Organization Certification Scheme on the Quality of Medicinal Products) issued by the manufacturer certifying that the product complies with requirements of the marketing authorization and signed by the person responsible for releasing the batch/lot.

§ 26.12 Nature of recognition of inspection reports.

(a) Inspection reports (containing information as established under § 26.8), including a good manufacturing practice (GMP) compliance assessment, prepared by authorities listed as equivalent, will be provided to the authority of the importing party. Based on the determination of equivalence in light of the experience gained, these inspection reports will normally be endorsed by the authority of the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in an inspection report, quality defects identified in the postmarket surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the authority of the importing party may request clarification from the authority of the exporting party which may lead to a request for reinspection. The authorities will endeavor to respond to requests for clarification in a timely manner.

(b) Where divergence is not clarified in this process, an authority of the importing country may carry out an inspection of the production facility.

§ 26.13 Transmission of postapproval inspection reports.

Postapproval good manufacturing practice (GMP) inspection reports concerning products covered by this subpart will be transmitted to the authority of the importing country within 60 calendar days of the request. Should a new inspection be needed, the inspection report will be transmitted within 90 calendar days of the request.

§ 26.14 Transmission of preapproval inspection reports.

(a) A preliminary notification that an inspection may have to take place will be made as soon as possible.

(b) Within 15 calendar days, the relevant authority will acknowledge receipt of the request and confirm its ability to carry out the inspection. In the European Community (EC), requests will be sent directly to the relevant authority, with a copy to the European Agency for the Evaluation of Medicinal Products (EMEA). If the authority receiving the request cannot carry out the inspection as requested, the requesting authority shall have the right to conduct the inspection.

(c) Reports of preapproval inspections will be sent within 45 calendar days of the request that transmitted the appropriate information and detailed the precise issues to be addressed during the inspection. A shorter time may be necessary in exceptional cases and these will be described in the request.

§ 26.15 Monitoring continued equivalence.

Monitoring activities for the purpose of maintaining equivalence shall include review of the exchange of inspection reports and their quality and timeliness; performance of a limited number of joint inspections; and the conduct of common training sessions.

§ 26.16 Suspension.

(a) Each party has the right to contest the equivalence of a regulatory authority. This right will be exercised in an objective and reasoned manner in writing to the other party.

(b) The issue shall be discussed in the Joint Sectoral Committee promptly upon such notification. Where the Joint Sectoral Committee determines that verification of equivalence is required, it may be carried out jointly by the parties in a timely manner, under § 26.6.

(c) Efforts will be made by the Joint Sectoral Committee to reach unanimous consent on the appropriate action. If agreement to suspend is reached in the Joint Sectoral Committee, an authority may be suspended immediately thereafter. If no agreement is reached in the Joint Sectoral Committee, the matter is referred to the Joint Committee as described in § 26.73. If no unanimous consent is reached within 30 days after such notification, the contested authority will be suspended.

(d) Upon the suspension of authority previously listed as equivalent, a party

is no longer obligated to normally endorse the inspection reports of the suspended authority. A party shall continue to normally endorse the inspection reports of that authority prior to suspension, unless the authority of the receiving party decides otherwise based on health or safety considerations. The suspension will remain in effect until unanimous consent has been reached by the parties on the future status of that authority.

§ 26.17 Role and composition of the Joint Sectoral Committee.

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

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

(1) Making a joint assessment, which must be agreed by both parties, of the equivalence of the respective authorities;

(2) Developing and maintaining the list of equivalent authorities, including any limitation in terms of inspecting type or products, and communicating the list to all authorities and the Joint Committee;

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

(4) Consideration of the issue of suspension.

(d) The Joint Sectoral Committee shall meet at the request of either party and, unless the cochairs otherwise agree, at least once each year. The Joint Committee will be kept informed of the agenda and conclusions of meetings of the Joint Sectoral Committee.

§ 26.18 Regulatory collaboration.

(a) The parties and authorities shall inform and consult one another, as permitted by law, on 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 B of this subpart.

§ 26.19 Information relating to quality aspects.

The authorities will establish an appropriate means of exchanging information on any confirmed problem reports, corrective actions, recalls, rejected import consignments and other regulatory and enforcement problems for products subject to this subpart.

§ 26.20 Alert system.

(a) The details of an alert system will be developed during the transitional period. The system will be maintained in place at all times. Elements to be considered in developing such a system are described in Appendix E of this subpart.

(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, recalls, counterfeiting, and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

§ 26.21 Safeguard clause.

Each party recognizes that the importing country has a right to fulfill its legal responsibilities by taking actions necessary to ensure the protection of human and animal health at the level of protection it deems appropriate. This includes the suspension of the distribution, product detention at the border of the importing country, withdrawal of the batches and any request for additional information or inspection as provided in § 26.12.

Appendix A of Subpart A—List of Applicable Laws, Regulations, and Administrative Provisions

1. For the European Community:

[Copies of EC documents may be obtained from the European Document Research, 1100 17th St. NW., suite 301, Washington, DC 20036. EC documents may be viewed on the European Commission Pharmaceuticals Units web site at ''http://dg3.eudra.org.'']

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation, or administrative action relating to proprietary medicinal products as extended, widened, and amended.

Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products as extended, widened and amended.

Council Directive 81/851/EEC of 6 November 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products as widened and amended.

Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products.

Council Regulation No (EEC) 2309/93 of 23 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products.

Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use & Guide to Good Distribution Practice.

Current version of the Guide to Good Manufacturing Practice, Rules Governing Medicinal Products in the European Community, Volume IV.

2. For the United States :

[Copies of FDA documents may be obtained from the Government Printing Office, 1510 H St. NW., Washington, DC 20005. FDA documents, except the FDA Compliance Program Guidance Manual, may be viewed on FDA's Internet web site at ''http://www.FDA.gov''.]

Relevant sections of the United States Federal Food, Drug, and Cosmetic Act and the United States Public Health Service Act.

Relevant sections of Title 21, United States Code of Federal Regulations (CFR) Parts 1–99, Parts 200–299, Parts 500–599, and Parts 600–799.

Relevant sections of the FDA Investigations Operations Manual, the FDA Regulatory Procedures Manual, the FDA Compliance Policy Guidance Manual, the FDA Compliance Program Guidance Manual, and other FDA guidances.

Appendix B of Subpart A—List of Authorities

1. For the United States:

In the United States, the regulatory authority is the Food and Drug Administration.

2. For the European Community:

In the European Community, the regulatory authorities are the following :

Austria: Bundesministerium Fur Arbeit, Gesundheit, und Soziales, Wien.

Belgium: Ministèrie van Sociale Zakem, Volksgezondheid en Leefmilieu /Ministere des Affaires Sociales, Sante Publique et Environment/ Algemeine Farmaceutische Inspectie, Inspection Generale de la Pharmacie, Bruxelles, Brussel.

Denmark: Laegemiddelstryelsen, (Danish Medicines Agency), Bronshoj.

Finland: Laakelaittos/Lakemedelsverket (National Agency for Medicines), Helsinki.

France: Agence du Médicament, Direction de l'inspection et des établissements, Saint Denis. (Human). Agence Nationale du Médicament Vétérinaire, Fougères (Veterinary).

Germany: Bundesgesundheitsministerium, Bonn. Paul-Ehrlich Institut, Langen (biologicals only). Zustandige Behorden der 16 Bundeslander: Bayern, Berlin Brandenberg, Bremen, Hamburg, Hessen, Niedersachsen, Nordrhein-Westfalen, Rheinland-Pfalz, Mecklenberg-Vorpommern, Saarland, Sachsen, Sachsenanhalt, Schleswog-Holstein, Thuringen.

Greece: Ministry of Health and Welfare, National Drug Organisation (E.O.F.), Athens.

Ireland: Irish Medicines Board, Dublin.

Italy: Ministero della Sanità, Dipartimento Farmaci e Farmacovigilanza, Roma. (Human). Ministero della Sanità, Dipartimento alimenti e nutrizione e sanità pubblica veterinaria - Div. IX, Roma (Veterinary).
Luxembourg: Direction de la Santé, Division de la Pharmacie et des Médicaments, Luxembourg.
The Netherlands: Staatstoezicht op de Volksgezondheid, Inspectie voor de Gezondheidszorg, Rijswijk.
Portugal: Instituto da Farmácia e do Medicamento (INFARMED), Lisboa.
Spain: Ministerio Sanidad y Consumo, Subdirección. General de Control Farmacéutico, Madrid. (Human) Ministerio de Agricultura Pesca y Alimentación, Madrid, (Veterinary).
Sweden: Läkemedelsverket (Medical Products Agency), Uppsala.
United Kingdom: Medicines Control Agency, London. Veterinary Medicines Directorate, Addlestone.
European Union: European Commission, Brussels. European Agency for the Evaluation of Medicinal Products (EMEA), London.

Appendix C of Subpart A—Indicative List of Products Covered by Subpart A

Recognizing that precise definition of medicinal products and drugs are to be found in the legislations referred to above, an indicative list of products covered by this arrangement is given below:

- human medicinal products including prescription and nonprescription drugs;
- human biologicals including vaccines, and immunologicals;
- veterinary pharmaceuticals, including prescription and nonprescription drugs, with the exclusion of veterinary immunologicals (Under 9 CFR 101.2 ''veterinary immunologicals'' are referred to as ''veterinary biologicals.'');
- premixes for the preparation of veterinary medicated feeds (EC), Type A medicated articles for the preparation of veterinary medicated feeds (United States);
- intermediate products and active pharmaceutical ingredients or bulk pharmaceuticals (United States)/starting materials (EC).

Appendix D of Subpart A—Criteria for Assessing Equivalence for Post- and Preapproval

I. Legal/Regulatory authority and structures and procedures providing for post- and preapproval:

A. Appropriate statutory mandate and jurisdiction.
B. Ability to issue and update binding requirements on GMP's and guidance documents.
C. Authority to make inspections, review and copy documents, and to take samples and collect other evidence.
D. Ability to enforce requirements and to remove products found in violation of such requirements from the market.
E. Substantive current good manufacturing requirements.
F. Accountability of the regulatory authority.
G. Inventory of current products and manufacturers.
H. System for maintaining or accessing inspection reports, samples and other analytical data, and other firm/product information relating to matters covered by subpart A of this part.

II. Mechanisms in place to assure appropriate professional standards and avoidance of conflicts of interest.

III. Administration of the regulatory authority:

A. Standards of education/qualification and training.
B. Effective quality assurance systems measures to ensure adequate job performance.
C. Appropriate staffing and resources to enforce laws and regulations.

IV. Conduct of inspections:

A. Adequate preinspection preparation, including appropriate expertise of investigator/team, review of firm/product and databases, and availability of appropriate inspection equipment.
B. Adequate conduct of inspection, including statutory access to facilities, effective response to refusals, depth and competence of evaluation of operations, systems, and documentation; collection of evidence; appropriate duration of inspection and completeness of written report of observations to firm management.
C. Adequate postinspection activities, including completeness of inspectors' report, inspection report review where appropriate, and conduct of followup inspections and other activities where appropriate, assurance of preservation and retrieval of records.

V. Execution of regulatory enforcement actions to achieve corrections, designed to prevent future violations, and to remove products found in violation of requirements from the market.

VI. Effective use of surveillance systems:

A. Sampling and analysis.
B. Recall monitoring.
C. Product defect reporting system.
D. Routine surveillance inspections.
E. Verification of approved manufacturing process changes to marketing authorizations/approved applications.

VII. Additional specific criteria for preapproval inspections:

A. Satisfactory demonstration through a jointly developed and administered training program and joint inspections to assess the regulatory authorities' capabilities.
B. Preinspection preparation includes the review of appropriate records, including site plans and drug master file or similar documentation to enable adequate inspections.
C. Ability to verify chemistry, manufacturing, and control data supporting an application is authentic and complete.
D. Ability to assess and evaluate research and development data as scientifically sound, especially transfer technology of pilot, scale up and full scale production batches.
E. Ability to verify conformity of the onsite processes and procedures with those described in the application.
F. Review and evaluate equipment installation, operational and performance qualification data, and evaluate test method validation.

Appendix E of Subpart A—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:

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 :

Division of Emergency and Investigational Operations (DEIO), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Telephone 301–443–1240, Fax 301–443–3757.

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 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.

§ 26.38 Other transition period activities.

(a) During the transition period, the parties will jointly determine the necessary information which must be present in quality system and product evaluation reports.

(b) The parties will jointly develop a notification and alert system to be used in case of defects, recalls, and other problems concerning product quality that could necessitate additional actions (e.g., inspections by the parties of the importing country) or suspension of the distribution of the product.

§ 26.39 Equivalence assessment.

(a) In the final 6 months of the transition period, the parties shall proceed to a joint assessment of the equivalence of the conformity assessment bodies (CAB's) that participated in the confidence building activities. CAB's will be determined to be equivalent provided they have demonstrated proficiency through the submission of a sufficient number of adequate reports. CAB's may be determined to be equivalent with regard to the ability to perform any type of quality system or product evaluation covered by this subpart and with regard to any type of product covered by this subpart. The parties shall develop a list contained in Appendix E of this subpart of CAB's determined to be equivalent which shall contain a full explanation of the scope of the equivalency determination, including any appropriate limitations, with regard to performing any type of quality system or product evaluation.

(b) The parties shall allow CAB's not listed for participation in this subpart, or listed for participation only as to certain types of evaluations, to apply for participation in this subpart once the necessary measures have been taken or sufficient experience has been gained, in accordance with § 26.46.

(c) Decisions concerning the equivalence of CAB's must be agreed to by both parties.

§ 26.40 Start of the operational period.

(a) The operational period will start at the end of the transition period after the parties have developed the list of conformity assessment bodies (CAB's) 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 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 phase, 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 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 and utilize the results of those activities to the extent possible. Such participation involves developing and reviewing documents developed by the Global Harmonization Task Force 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 could necessitate additional controls or suspension of the distribution of the product.

Appendix A of Subpart B—Relevant Legislation, Regulations and Procedures

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

[Copies of EC documents may be obtained from the European Document Research, 1100 17th St. NW., suite 301, Washington, DC 20036.]

a. Council Directive 90/385/EEC of 20 June 1990 on active implantable medical devices
OJ No. L 189, 20.7. 1990, p. 17. Conformity assessment procedures.
Annex 2 (with the exception of section 4)
Annex 4
Annex 5

b. Council Directive 93/42/EEC of 14 June 1993 on Medical Devices OJ No. L 169,12.7.1993, p.1. Conformity assessment procedures.
Annex 2 (with the exception of section 4)
Annex 3
Annex 4
Annex 5
Annex 6

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

[Copies of FDA documents may be obtained from the Government Printing Office, 1510 H St. NW., Washington, DC 20005. FDA documents may be viewed on FDA's Internet web site at ''http://www.fda.gov''.]

a. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 *et seq.*

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.

d. Medical Devices; Third Party Review of Selected Premarket Notifications; Pilot Program, 61 FR 14789-14796 (April 3, 1996).

Appendix B of Subpart B—Scope of Product Coverage

1. Initial Coverage of the Transition Period

Upon entry into force of this subpart as described in § 26.80 (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

b. Those for which review may be based primarily on international standards, in order for the parties to gain the requisite experience.

The corresponding additional product lists will be phased in on an annual basis. The parties may consult with industry and other interested parties in determining which products will be added.

3. Commencement of the Operational Period

a. At the commencement of the operational period, product coverage shall extend to all Class I/II products covered during the transition period.

b. FDA will expand the program to categories of Class II devices as is consistent with the results of the pilot, and with FDA's ability to write guidance documents if the device pilot for the third party review of medical devices is successful. The MRA will cover to the maximum extent feasible all Class II devices listed in Table 3 for which FDA-accredited third party review is available in the United States.

4. Unless explicitly included by joint decision of the parties, this part does not cover any U.S. Class II-tier 3 or any Class III product under either system.

[FDA is codifying the lists of medical devices contained in the following tables as they appear in the medical device annex of the ''Agreement on Mutual Recognition Between the United States of America and the European Community.'' As a result of the Food and Drug Administration Modernization Act of 1997, however, the medical devices included in these tables will change.]

TABLE 1.—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD[1]

21 CFR Section No.	Regulation Name Product Code—Device Name
Anesthesiology Panel (21 CFR Part 868)	
868.1910	Esophageal Stethoscope BZW—Stethoscope, Esophageal
868.5620	Breathing Mouthpiece BYP—Mouthpiece, Breathing
868.5640	Medicinal Nonventilatory Nebulizer (Atomizer) CCQ—Nebulizer, Medicinal, Nonventilatory (Atomizer)
868.5675	Rebreathing Device BYW—Device, Rebreathing
868.5700	Nonpowered Oxygen Tent FOG—Hood, Oxygen, Infant BYL—Tent, Oxygen
868.6810	Tracheobronchial Suction Catheter BSY—Catheters, Suction, Tracheobronchial

TABLE 1.—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD[1]—Continued

21 CFR Section No.	Regulation Name Product Code—Device Name
Cardiovascular Panel	
(None)	
Dental Panel (21 CFR Part 872)	
872.3400	Karaya and Sodium Borate With or Without Acacia Denture Adhesive
	KOM—Adhesive, Denture, Acacia and Karaya With Sodium Borate
872.3700	Dental Mercury (U.S.P.)
	ELY—Mercury
872.4200	Dental Handpiece and Accessories
	EBW—Controller, Food, Handpiece and Cord
	EFB—Handpiece, Air-Powered, Dental
	EFA—Handpiece, Belt and/or Gear Driven, Dental
	EGS—Handpiece, Contra- and Right-Angle Attachment, Dental
	EKX—Handpiece, Direct Drive, AC-Powered
	EKY—Handpiece, Water-Powered
872.6640	Dental Operative Unit and Accessories
	EIA—Unit, Operative Dental
Ear, Nose, and Throat Panel (21 CFR Part 874)	
874.1070	Short Increment Sensitivity Index (SISI) Adapter
	ETR—Adapter, Short Increment Sensitivity Index (SISI)
874.1500	Gustometer
	ETM—Gustometer
874.1800	Air or Water Caloric Stimulator
	KHH—Stimulator, Caloric-Air
	ETP—Stimulator, Caloric-Water
874.1925	Toynbee Diagnostic Tube
	ETK—Tube, Toynbee Diagnostic
874.3300	Hearing Aid
	LRB—Face Plate Hearing-Aid
	ESD—Hearing-aid, Air-Conduction
874.4100	Epistaxis Balloon
	EMX—Balloon, Epistaxis
874.5300	ENT Examination and Treatment Unit
	ETF—Unit, Examining/Treatment, ENT
874.5550	Powered Nasal Irrigator
	KMA—Irrigator, Powered Nasal
874.5840	Antistammering Device
	KTH—Device, Anti-Stammering
Gastroenterology—Urology Panel (21 CFR Part 876)	
876.5160	Urological Clamp for Males
	FHA—Clamp, Penile
876.5210	Enema Kit
	FCE—Kit, Enema, (for Cleaning Purpose)
876.5250	Urine Collector and Accessories
	FAQ—Bag, Urine Collection, Leg, for External Use
General Hospital Panel (21 CFR Part 880)	
880.5270	Neonatal Eye Pad
	FOK—Pad, Neonatal Eye
880.5420	Pressure Infusor for an I.V. Bag
	KZD—Infusor, Pressure, for I.V. Bags
880.5680	Pediatric Position Holder
	FRP—Holder, Infant Position
880.6250	Patient Examination Glove
	LZB—Finger Cot
	FMC—Glove, Patient Examination
	LYY—Glove, Patient Examination, Latex
	LZA—Glove, Patient Examination, Poly
	LZC—Glove, Patient Examination, Speciality
	LYZ—Glove, Patient Examination, Vinyl
880.6375	Patient Lubricant
	KMJ—Lubricant, Patient
880.6760	Protective Restraint
	BRT—Restraint, Patient, Conductive
	FMQ—Restraint, Protective
Neurology Panel (21 CFR Part 882)	
882.1030	Ataxiagraph
	GWW—Ataxiagraph
882.1420	Electroencephalogram (EEG) Signal Spectrum Analyzer
	GWS—Analyzer, Spectrum, Electroencephalogram Signal

TABLE 1.—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD[1]—Continued

21 CFR Section No.	Regulation Name Product Code—Device Name
882.4060	Ventricular Cannula HCD—Cannula, Ventricular
882.4545	Shunt System Implantation Instrument GYK—Instrument, Shunt System Implantation
882.4650	Neurosurgical Suture Needle HAS—Needle, Neurosurgical Suture
882.4750	Skull Punch GXJ—Punch, Skull
Obstetrics and Gynecology Panel	
(None)	
Ophthalmology Panel (21 CFR Part 886)	
886.1780	Retinoscope HKM—Retinoscope, Battery-Powered
886.1940	Tonometer Sterilizer HKZ—Sterilizer, Tonometer
886.4070	Powered Corneal Burr HQS—Burr, Corneal, AC-Powered HOG—Burr, Corneal, Battery-Powered HRG—Engine, Trephine, Accessories, AC-Powered HFR—Engine, Trephine, Accessories, Battery-Powered HLD—Engine, Trephine, Accessories, Gas-Powered
886.4370	Keratome HNO—Keratome, AC-Powered HMY—Keratome, Battery-Powered
886.5850	Sunglasses (Nonprescription) HQY—Sunglasses (Nonprescription Including Photosensitive)
Orthopedic Panel (21 CFR Part 888)	
888.1500	Goniometer KQX—Goniometer, AC-Powered
888.4150	Calipers for Clinical Use KTZ—Caliper
Physical Medicine Panel (21 CFR Part 890)	
890.3850	Mechanical Wheelchair LBE—Stroller, Adaptive IOR—Wheelchair, Mechanical
890.5180	Manual Patient Rotation Bed INY—Bed, Patient Rotation, Manual
890.5710	Hot or Cold Disposable Pack IMD—Pack, Hot or Cold, Disposable
Radiology Panel (21 CFR Part 892)	
892.1100	Scintillation (Gamma) Camera IYX—Camera, Scintillation (Gamma)
892.1110	Positron Camera IZC—Camera, Positron
892.1300	Nuclear Rectilinear Scanner IYW—Scanner, Rectilinear, Nuclear
892.1320	Nuclear Uptake Probe IZD—Probe, Uptake, Nuclear
892.1330	Nuclear Whole Body Scanner JAM—Scanner, Whole Body, Nuclear
892.1410	Nuclear Electrocardiograph Synchronizer IVY—Synchronizer, Electrocardiograph, Nuclear
892.1890	Radiographic Film Illuminator IXC—Illuminator, Radiographic-Film JAG—Illuminator, Radiographic-Film, Explosion-Proof
892.1910	Radiographic Grid IXJ—Grid, Radiographic
892.1960	Radiographic Intensifying Screen WAM—Screen, Intensifying, Radiographic
892.1970	Radiographic ECG/Respirator Synchronizer IXO—Synchronizer, ECG/Respirator, Radiographic
892.5650	Manual Radionuclide Applicator System IWG—System, Applicator, Radionuclide, Manual
General and Plastic Surgery Panel (21 CFR Part 878)	
878.4200	Introduction/Drainage Catheter and Accessories KGZ—Accessories, Catheter GCE—Adaptor, Catheter FGY—Cannula, Injection GBA—Catheter, Balloon Type

TABLE 1.—CLASS I PRODUCTS REQUIRING PREMARKET EVALUATIONS IN THE UNITED STATES, INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD[1]—Continued

21 CFR Section No.	Regulation Name
	Product Code—Device Name
	GBZ—Catheter, Cholangiography
	GBQ—Catheter, Continuous Irrigation
	GBY—Catheter, Eustachian, General & Plastic Surgery
	JCY—Catheter, Infusion
	GBX—Catheter, Irrigation
	GBP—Catheter, Multiple Lumen
	GBO—Catheter, Nephrostomy, General & Plastic Surgery
	GBN—Catheter, Pediatric, General & Plastic Surgery
	GBW—Catheter, Peritoneal
	GBS—Catheter, Ventricular, General & Plastic Surgery
	GCD—Connector, Catheter
	GCC—Dilator, Catheter
	GCB—Needle, Catheter
878.4320	Removable Skin Clip
	FZQ—Clip, Removable (Skin)
878.4460	Surgeon's Gloves
	KGO—Surgeon's Gloves
878.4680	Nonpowered, Single Patient, Portable Suction Apparatus
	GCY—Apparatus, Suction, Single Patient Use, Portable, Nonpowered
878.4760	Removable Skin Staple
	GDT—Staple, Removable (Skin)
878.4820	AC–Powered, Battery-Powered, and Pneumatically Powered Surgical Instrument Motors and Accessories/Attachments
	GFG—Bit, Surgical
	GFA—Blade, Saw, General & Plastic Surgery
	DWH—Blade, Saw, Surgical, Cardiovascular
	BRZ—Board, Arm (With Cover)
	GFE—Brush, Dermabrasion
	GFF—Bur, Surgical, General & Plastic Surgery
	KDG—Chisel (Osteotome)
	GFD—Dermatome
	GFC—Driver, Surgical, Pin
	GFB—Head, Surgical, Hammer
	GEY—Motor, Surgical Instrument, AC-Powered
	GET—Motor, Surgical Instrument, Pneumatic Powered
	DWI—Saw, Electrically Powered
	KFK—Saw, Pneumatically Powered
	HAB—Saw, Powered, and Accessories
878.4960	Air or AC-Powered Operating Table and Air or AC-Powered Operating Chair & Accessories
	GBB—Chair, Surgical, AC-Powered
	FQO—Table, Operating-Room, AC-Powered
	GDC—Table, Operating-Room, Electrical
	FWW—Table, Operating-Room, Pneumatic
	JEA—Table, Surgical with Orthopedic Accessories, AC-Powered
880.5090	Liquid Bandage
	KMF—Bandage, Liquid

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at ''http://www.fda.gov/cdrh/prodcode.html''.

TABLE 2.—CLASS II MEDICAL DEVICES INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD (UNITED STATES TO DEVELOP GUIDANCE DOCUMENTS IDENTIFYING U.S. REQUIREMENTS AND EUROPEAN COMMUNITY (EC) TO IDENTIFY STANDARDS NEEDED TO MEET EC REQUIREMENTS)[1]

Panel	21 CFR Section No.	Regulation Name
		Product Code—Device Name
RA	892.1000	Magnetic Resonance Diagnostic Device
		MOS—COIL, Magnetic Resonance, Specialty
		LNH—System, Nuclear Magnetic Resonance Imaging
		LNI—System, Nuclear Magnetic Resonance Spectroscopic
Diagnostic Ultrasound:		
RA	892.1540	Nonfetal Ultrasonic Monitor
		JAF—Monitor, Ultrasonic, Nonfetal
RA	892.1550	Ultrasonic Pulsed Doppler Imaging System
		IYN—System, Imaging, Pulsed Doppler, Ultrasonic

TABLE 2.—CLASS II MEDICAL DEVICES INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD (UNITED STATES TO DEVELOP GUIDANCE DOCUMENTS IDENTIFYING U.S. REQUIREMENTS AND EUROPEAN COMMUNITY (EC) TO IDENTIFY STANDARDS NEEDED TO MEET EC REQUIREMENTS)[1]—Continued

Panel	21 CFR Section No.	Regulation Name
		Product Code—Device Name
RA	892.1560	Ultrasonic Pulsed Echo Imaging System IYO—System, Imaging, Pulsed Echo, Ultrasonic
RA	892.1570	Diagnostic Ultrasonic Transducer ITX—Transducer, Ultrasonic, Diagnostic
Diagnostic X-Ray Imaging Devices (except mammographic x-ray systems):		
RA	892.1600	Angiographic X-Ray System IZI—System, X-Ray, Angiographic
RA	892.1650	Image-Intensified Fluoroscopic X-Ray System MQB—Solid State X-Ray Imager (Flat Panel/Digital Imager) JAA—System, X-Ray, Fluoroscopic, Image-Intensified
RA	892.1680	Stationary X-Ray System KPR—System, X-Ray, Stationary
RA	892.1720	Mobile X-Ray System IZL—System, X-Ray, Mobile
RA	892.1740	Tomographic X-Ray System IZF—System, X-Ray, Tomographic
RA	892.1750	Computed Tomography X-Ray System JAK—System, X-Ray, Tomography, Computed
ECG-Related Devices:		
CV	870.2340	Electrocardiograph DPS—Electrocardiograph MLC—Monitor, ST Segment
CV	870.2350	Electrocardiograph Lead Switching Adaptor DRW—Adaptor, Lead Switching, Electrocardiograph
CV	870.2360	Electrocardiograph Electrode DRX—Electrode, Electrocardiograph
CV	870.2370	Electrocardiograph Surface Electrode Tester KRC—Tester, Electrode, Surface, Electrocardiographic
NE	882.1400	Electroencephalograph GWQ—Electroencephalograph
HO	880.5725	Infusion Pump (external only) MRZ—Accessories, Pump, Infusion FRN—Pump, Infusion LZF—Pump, Infusion, Analytical Sampling MEB—Pump, Infusion, Elastomeric LZH—Pump, Infusion, Enteral MHD—Pump, Infusion, Gallstone Dissolution LZG—Pump, Infusion, Insulin MEA—Pump, Infusion, PCA
Ophthalmic Instruments:		
OP	886.1570	Ophthalmoscope HLI—Ophthalmoscope, AC-Powered HLJ—Ophthalmoscope, Battery-Powered
OP	886.1780	Retinoscope HKL—Retinoscope, AC-Powered
OP	886.1850	AC-Powered Slit-Lamp Biomicroscope HJO—Biomicroscope, Slit-Lamp, AC-Powered
OP	886.4150	Vitreous Aspiration and Cutting Instrument MMC—Dilator, Expansive Iris (Accessory) HQE—Instrument, Vitreous Aspiration and Cutting, AC-Powered HKP—Instrument, Vitreous Aspiration and Cutting, Battery-Powered MLZ—Vitrectomy, Instrument Cutter
OP	886.4670	Phacofragmentation System HQC—Unit, Phacofragmentation
SU	878.4580	Surgical Lamp HBI—Illuminator, Fiberoptic, Surgical Field FTF—Illuminator, Nonremote FTG—Illuminator, Remote HJE—Lamp, Fluorescein, AC-Powered FQP—Lamp, Operating-Room FTD—Lamp, Surgical GBC—Lamp, Surgical, Incandescent FTA—Light, Surgical, Accessories FSZ—Light, Surgical, Carrier FSY—Light, Surgical, Ceiling Mounted

TABLE 2.—CLASS II MEDICAL DEVICES INCLUDED IN SCOPE OF PRODUCT COVERAGE AT BEGINNING OF TRANSITION PERIOD (UNITED STATES TO DEVELOP GUIDANCE DOCUMENTS IDENTIFYING U.S. REQUIREMENTS AND EUROPEAN COMMUNITY (EC) TO IDENTIFY STANDARDS NEEDED TO MEET EC REQUIREMENTS)[1]—Continued

Panel	21 CFR Section No.	Regulation Name
		Product Code—Device Name
		FSX—Light, Surgical, Connector
		FSW—Light, Surgical, Endoscopic
		FST—Light, Surgical, Fiberoptic
		FSS—Light, Surgical, Floor Standing
		FSQ—Light, Surgical, Instrument
NE	882.5890	Transcutaneous Electrical Nerve Stimulator for Pain Relief
		GZJ—Stimulator, Nerve, Transcutaneous, For Pain Relief
		Noninvasive Blood Pressure Measurement Devices:
CV	870.1120	Blood Pressure Cuff
		DXQ—Cuff, Blood-Pressure
CV	870.1130	Noninvasive Blood Pressure Measurement System (except nonoscillometric)
		DXN—System, Measurement, Blood-Pressure, Noninvasive
HO	880.6880	Steam Sterilizer (greater than 2 cubic feet)
		FLE—Sterilizer, Steam
Clinical Thermometers:		
HO	880.2910	Clinical Electronic Thermometer (except tympanic or pacifier)
		FLL—Thermometer, Electronic, Clinical
AN	868.5630	Nebulizer
		CAF—Nebulizer (Direct Patient Interface)
AN	868.5925	Powered Emergency Ventilator
Hypodermic Needles and Syringes (except antistick and self-destruct):		
HO	880.5570	Hypodermic Single Lumen Needle
		MMK—Container, Sharpes
		FMI—Needle, Hypodermic, Single Lumen
		MHC—Port, Intraosseous, Implanted
HO	880.5860	Piston Syringe
		FMF—Syringe, Piston
OR	888.3020	Intramedullary Fixation Rod
		HSB—ROD, Fixation, Intramedullary and Accessories
External Fixators (except devices with no external components):		
OR	888.3030	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
		KTT—Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
OR	888.3040	Smooth or Threaded Metallic Bone Fixation Fastener
		JEC—Component, Traction, Invasive
		HTY—Pin, Fixation, Smooth
		JDW—Pin, Fixation, Threaded
Selected Dental Materials:		
DE	872.3060	Gold-Based Alloys and Precious Metal Alloys for Clinical Use
		EJT—Alloy, Gold Based, For Clinical Use
		EJS—Alloy, Precious Metal, For Clinical Use
DE	872.3200	Resin Tooth Bonding Agent
		KLE—Agent, Tooth Bonding, Resin
DE	872.3275	Dental Cement
		EMA—Cement, Dental
		EMB—Zinc Oxide Eugenol
DE	872.3660	Impression Material
		ELW—Material, Impression
DE	872.3690	Tooth Shade Resin Material
		EBF—Material, Tooth Shade, Resin
DE	872.3710	Base Metal Alloy
		EJH—Metal, Base
Latex Condoms:		
OB	884.5300	Condom
		HIS—Condom

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at ''http://www.fda.gov/cdrh/prodcode.html''.

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]

Product Family	21 CFR Section No	Device Name	Tier
Anesthesiology Panel			
Anesthesia Devices	868.5160	Gas machine for anesthesia or analgesia	2
	868.5270	Breathing system heater	2
	868.5440	Portable oxygen generator	2
	868.5450	Respiratory gas humidifier	2
	868.5630	Nebulizer	2
	868.5710	Electrically powered oxygen tent	2
	868.5880	Anesthetic vaporizer	2
Gas Analyser	868.1040	Powered Algesimeter	2
	868.1075	Argon gas analyzer	2
	868.1400	Carbon dioxide gas analyzer	2
	868.1430	Carbon monoxide gas analyzer	2
	868.1500	Enflurane gas analyzer	2
	868.1620	Halothane gas analyzer	2
	868.1640	Helium gas analyzer	2
	868.1670	Neon gas analyzer	2
	868.1690	Nitrogen gas analyzer	2
	868.1700	Nitrous oxide gas analyzer	2
	868.1720	Oxygen gas analyzer	2
	868.1730	Oxygen uptake computer	2
Peripheral Nerve Stimulators	868.2775	Electrical peripheral nerve stimulator	2
Respiratory Monitoring	868.1750	Pressure plethysmograph	2
	868.1760	Volume plethysmograph	2
	868.1780	Inspiratory airway pressure meter	2
	868.1800	Rhinoanemometer	2
	868.1840	Diagnostic spirometer	2
	868.1850	Monitoring spirometer	2
	868.1860	Peak-flow meter for spirometry	2
	868.1880	Pulmonary-function data calculator	2
	868.1890	Predictive pulmonary-function value calculator	2
	868.1900	Diagnostic pulmonary-function interpretation calculator	2
	868.2025	Ultrasonic air embolism monitor	2
	868.2375	Breathing frequency monitor (except apnea detectors)	2
	868.2480	Cutaneous carbon dioxide ($PcCO_2$) monitor	2
	868.2500	Cutaneous oxygen monitor (for an infant not under gas anesthesia)	2
	868.2550	Pneumotachomometer	2
	868.2600	Airway pressure monitor	2
	868.5665	Powered percussor	2
	868.5690	Incentive spirometer	2
Ventilator	868.5905	Noncontinuous ventilator (IPPB)	2
	868.5925	Powered emergency ventilator	2
	868.5935	External negative pressure ventilator	2
	868.5895	Continuous ventilator	2
	868.5955	Intermittent mandatory ventilation attachment	2
	868.6250	Portable air compressor	2
Cardiovascular Panel			
Cardiovascular Diagnostic	870.1425	Programmable diagnostic computer	2
	870.1450	Densitometer	2
	870.2310	Apex cardiograph (vibrocardiograph)	2
	870.2320	Ballistocardiograph	2
	870.2340	Electrocardiograph	2
	870.2350	Electrocardiograph lead switching adaptor	1
	870.2360	Electrocardiograph electrode	2
	870.2370	Electrocardiograph surface electrode tester	2
	870.2400	Vectorcardiograph	1
	870.2450	Medical cathode-ray tube display	1

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	870.2675	Oscillometer	2
	870.2840	Apex cardiographic transducer	2
	870.2860	Heart sound transducer	2
Cardiovascular Monitoring		Valve, pressure relief, cardiopulmonary bypass	
	870.1100	Blood pressure alarm	2
	870.1110	Blood pressure computer	2
	870.1120	Blood pressure cuff	2
	870.1130	Noninvasive blood pressure measurement system	2
	870.1140	Venous blood pressure manometer	2
	870.1220	Electrode recording catheter or electrode recording probe	2
	870.1270	Intracavitary phonocatheter system	2
	870.1875	Stethoscope (electronic)	2
	870.2050	Biopotential amplifier and signal conditioner	2
	870.2060	Transducer signal amplifier and conditioner	2
	870.2100	Cardiovascular blood flow-meter	2
	870.2120	Extravascular blood flow probe	2
	870.2300	Cardiac monitor (including cardiotachometer and rate alarm)	2
	870.2700	Oximeter	2
	870.2710	Ear oximeter	2
	870.2750	Impedance phlebograph	2
	870.2770	Impedance plethysmograph	2
	870.2780	Hydraulic, pneumatic, or photoelectric plethysmographs	2
	870.2850	Extravascular blood pressure transducer	2
	870.2870	Catheter tip pressure transducer	2
	870.2880	Ultrasonic transducer	2
	870.2890	Vessel occlusion transducer	2
	870.2900	Patient transducer and electrode cable (including connector)	2
	870.2910	Radiofrequency physiological signal transmitter and receiver	2
	870.2920	Telephone electrocardiograph transmitter and receiver	2
	870.4205	Cardiopulmonary bypass bubble detector	2
	870.4220	Cardiopulmonary bypass heart-lung machine console	2
	870.4240	Cardiovascular bypass heat exchanger	2
	870.4250	Cardiopulmonary bypass temperature controller	2
	870.4300	Cardiopulmonary bypass gas control unit	2
	870.4310	Cardiopulmonary bypass coronary pressure gauge	2
	870.4330	Cardiopulmonary bypass on-line blood gas monitor	2
	870.4340	Cardiopulmonary bypass level sensing monitor and/or control	2
	870.4370	Roller-type cardiopulmonary bypass blood pump	2
	870.4380	Cardiopulmonary bypass pump speed control	2
	870.4410	Cardiopulmonary bypass in-line blood gas sensor	2
Cardiovascular Therapeutic	870.5050	Patient care suction apparatus	2
	870.5900	Thermal regulation system	2
Defibrillator	870.5300	DC-defribrillator (including paddles)	2
	870.5325	Defibrillator tester	2

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
Echocardiograph	870.2330	Echocardiograph	2
Pacemaker & Accessories	870.1750	External programmable pacemaker pulse generator	2
	870.3630	Pacemaker generator function analyzer	2
	870.3640	Indirect pacemaker generator function analyzer	2
	870.3720	Pacemaker electrode function tester	2
Miscellaneous	870.1800	Withdrawal-infusion pump	2
	870.2800	Medical magnetic tape recorder	2
	None	Batteries, rechargeable, class II devices	
Dental Panel			
Dental Equipment	872.1720	Pulp tester	2
	872.1740	Caries detection device	2
	872.4120	Bone cutting instrument and accessories	2
	872.4465	Gas-powered jet injector	2
	872.4475	Spring-powered jet injector	2
	872.4600	Intraoral ligature and wire lock	2
	872.4840	Rotary scaler	2
	872.4850	Ultrasonic scaler	2
	872.4920	Dental electrosurgical unit and accessories	2
	872.6070	Ultraviolet activator for polymerization	2
	872.6350	Ultraviolet detector	2
Dental Material	872.3050	Amalgam alloy	2
	872.3060	Gold-based alloys and precious metal alloys for clinical use	2
	872.3200	Resin tooth bonding agent	2
	872.3250	Calcium hydroxide cavity liner	2
	872.3260	Cavity varnish	2
	872.3275	Dental cement (other than zinc oxide-eugenol)	2
	872.3300	Hydrophilic resin coating for dentures	2
	872.3310	Coating material for resin fillings	2
	872.3590	Preformed plastic denture tooth	2
	872.3660	Impression material	2
	872.3690	Tooth shade resin material	2
	872.3710	Base metal alloy	2
	872.3750	Bracket adhesive resin and tooth conditioner	2
	872.3760	Denture relining, repairing, or rebasing resin	2
	872.3765	Pit and fissure sealant and conditioner	2
	872.3770	Temporary crown and bridge resin	2
	872.3820	Root canal filling resin (other than chloroform use)	2
	872.3920	Porcelain tooth	2
Dental X-ray	872.1800	Extraoral source x-ray system	2
	872.1810	Intraoral source x-ray system	2
Dental Implants	872.4880	Intraosseous fixation screw or wire	2
	872.3890	Endodontic stabilizing splint	2
Orthodontic	872.5470	Orthodontic plastic bracket	2
Ear/Nose/Throat Panel			
Diagnostic Equipment	874.1050	Audiometer	2
	874.1090	Auditory impedance tester	2
	874.1120	Electronic noise generator for audiometric testing	2
	874.1325	Electroglottograph	2
	874.1820	Surgical nerve stimulator/locator	2
Hearing Aids	874.3300	Hearing aid (for bone-conduction)	2
	874.3310	Hearing aid calibrator and analysis system	2
	874.3320	Group hearing aid or group auditory trainer	2

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	874.3330	Master hearing aid	2
Surgical Equipment	874.4250	Ear, nose, and throat electric or pneumatic surgical drill	1
	874.4490	Argon laser for otology, rhinology, and laryngology	2
	874.4500	Ear, nose, and throat microsurgical carbon dioxide laser	2
Gastroenterology/Urology Panel			
Endoscope (including angioscopes, laparscopes, ophthalmic endoscopes)	876.1500	Endoscope and accessories	2
	876.4300	Endoscopic electrosurgical unit and accessories	2
Gastroenterology	876.1725	Gastrointestinal motility monitoring system	1
Hemodialysis	876.5600	Sorbent regenerated dialysate delivery system for hemodialysis	2
	876.5630	Peritoneal dialysis system and accessories	2
	876.5665	Water purification system for hemodialysis	2
	876.5820	Hemodialysis system and accessories	2
	876.5830	Hemodialyzer with disposable insert (kiil-type)	2
Lithotriptor	876.4500	Mechanical lithotriptor	2
Urology Equipment	876.1620	Urodynamics measurement system	2
	876.5320	Nonimplanted electrical continence device	2
	876.5880	Isolated kidney perfusion and transport system and accessories	2
General Hospital Panel			
Infusion Pumps and Systems	880.2420	Electronic monitor for gravity flow infusion systems	2
	880.2460	Electrically powered spinal fluid pressure monitor	2
	880.5430	Nonelectrically powered fluid injector	2
	880.5725	Infusion pump	2
Neonatal Incubators	880.5400	Neonatal incubator	2
	880.5410	Neonatal transport incubator	2
	880.5700	Neonatal phototherapy unit	2
Piston Syringes	880.5570	Hypodermic single lumen needle	1
	880.5860	Piston syringe (except antistick)	1
	880.6920	Syringe needle introducer	2
Miscellaneous	880.2910	Clinical electronic thermometer	2
	880.2920	Clinical mercury thermometer	2
	880.5100	AC-powered adjustable hospital bed	1
	880.5500	AC-powered patient lift	2
	880.6880	Steam sterilizer (greater than 2 cubic feet)	2
Neurology Panel			
	882.1020	Rigidity analyzer	2
	882.1610	Alpha monitor	2
Neuro-Diagnostic	882.1320	Cutaneous electrode	2
	882.1340	Nasopharyngeal electrode	2
	882.1350	Needle electrode	2
	882.1400	Electroencephalograph	2
	882.1460	Nystagmograph	2
	882.1480	Neurological endoscope	2
	882.1540	Galvanic skin response measurement device	2
	882.1550	Nerve conduction velocity measurement device	2
	882.1560	Skin potential measurement device	2
	882.1570	Powered direct-contact temperature measurement device	2

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	882.1620	Intracranial pressure monitoring device	2
	882.1835	Physiological signal amplifier	2
	882.1845	Physiological signal conditioner	2
	882.1855	Electroencephalogram (EEG) telemetry system	2
	882.5050	Biofeedback device	2
Echoencephalography	882.1240	Echoencephalograph	2
RPG	882.4400	Radiofrequency lesion generator	2
Neuro Surgery	none	Electrode, spinal epidural	2
	882.4305	Powered compound cranial drills, burrs, trephines, and their accessories	2
	882.4310	Powered simple cranial drills burrs, trephines, and their accessories	2
	882.4360	Electric cranial drill motor	2
	882.4370	Pneumatic cranial drill motor	2
	882.4560	Stereotaxic instrument	2
	882.4725	Radiofrequency lesion probe	2
	882.4845	Powered rongeur	2
	882.5500	Lesion temperature monitor	2
Stimulators	882.1870	Evoked response electrical stimulator	2
	882.1880	Evoked response mechanical stimulator	2
	882.1890	Evoked response photic stimulator	2
	882.1900	Evoked response auditory stimulator	2
	882.1950	Tremor transducer	2
	882.5890	Transcutaneous electrical nerve stimulator for pain relief	2
Obstetrics/Gynecology Panel			
Fetal Monitoring	884.1660	Transcervical endoscope (amnioscope) and accessories	2
	884.1690	Hysteroscope and accessories (for performance standards)	2
	884.2225	Obstetric-gynecologic ultrasonic imager	2
	884.2600	Fetal cardiac monitor	2
	884.2640	Fetal phonocardiographic monitor and accessories	2
	884.2660	Fetal ultrasonic monitor and accessories	2
	884.2675	Fetal scalp circular (spiral) electrode and applicator	1
	884.2700	Intrauterine pressure monitor and accessories	2
	884.2720	External uterine contraction monitor and accessories	2
	884.2740	Perinatal monitoring system and accessories	2
	884.2960	Obstetric ultrasonic transducer and accessories	2
Gynecological Surgery Equipment	884.1720	Gynecologic laparoscope and accessories	2
	884.4160	Unipolar endoscopic coagulator-cutter and accessories	2
	884.4550	Gynecologic surgical laser	2
	884.4120	Gynecologic electrocautery and accessories	2
	884.5300	Condom	2
Ophthalmic Implants	886.3320	Eye sphere implant	2
Contact Lens	886.1385	Polymethylmethacrylate (PMMA) diagnostic contact lens	2
	886.5916	Rigid gas permeable contact lens (daily wear only)	2
Diagnostic Equipment	886.1120	Opthalmic camera	1
	886.1220	Corneal electrode	1
	886.1250	Euthyscope (AC-powered)	1
	886.1360	Visual field laser instrument	1

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	886.1510	Eye movement monitor	1
	886.1570	Ophthalmoscope	1
	886.1630	AC-powered photostimulator	1
	886.1640	Ophthalmic preamplifier	1
	886.1670	Ophthalmic isotope uptake probe	2
	886.1780	Retinoscope (AC-powered device)	1
	886.1850	AC-powered slit lamp biomicroscope	1
	886.1930	Tonometer and accessories	2
	886.1945	Transilluminator (AC-powered device)	1
	886.3130	Ophthalmic conformer	2
(Diagnostic/Surgery Equipment)	886.4670	Phacofragmentation system	2
Ophthalmic Implants	886.3340	Extraocular orbital implant	2
	886.3800	Scleral shell	2
Surgical Equipment	880.5725	Infusion pump (performance standards)	2
	886.3100	Ophthalmic tantalum clip	2
	886.3300	Absorbable implant (scleral buckling method)	2
	886.4100	Radiofrequency electrosurgical cautery apparatus	2
	886.4115	Thermal cautery unit	2
	886.4150	Vitreous aspiration and cutting instrument	2
	886.4170	Cryophthalmic unit	2
	886.4250	Ophthalmic electrolysis unit (AC-powered device)	1
	886.4335	Operating headlamp (AC-powered device)	1
	886.4390	Ophthalmic laser	2
	886.4392	Nd:YAG laser for posterior capsulotomy	2
	886.4400	Electronic metal locator	1
	886.4440	AC-powered magnet	1
	886.4610	Ocular pressure applicator	2
	886.4690	Ophthalmic photocoagulator	2
	886.4790	Ophthalmic sponge	2
	886.5100	Ophthalmic beta radiation source	2
	none	Ophthalmoscopes, replacement batteries, hand-held	1
Orthopedic Panel			
Implants	888.3010	Bone fixation cerclage	2
	888.3020	Intramedullary fixation rod	2
	888.3030	Single/multiple component metallic bone fixation appliances and accessories	2
	888.3040	Smooth or threaded metallic bone fixation fastener	2
	888.3050	Spinal interlaminal fixation orthosis	2
	888.3060	Spinal intervertebral body fixation orthosis	2
Surgical Equipment	888.1240	AC-powered dynamometer	2
	888.4580	Sonic surgical instrument and accessories/attachments	2
	none	Accessories, fixation, spinal interlaminal	2
	none	Accessories, fixation, spinal intervertebral body	2
	none	Monitor, pressure, intracompartmental	1
	none	Orthosis, fixation, spinal intervertebral fusion	2
	none	Orthosis, spinal pedicle fixation	
	none	System, cement removal extraction	1

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
Physical Medicine Panel			
Diagnostic Equipment or (Therapy) Therapeutic Equipment	890.1225	Chronaximeter	2
	890.1375	Diagnostic electromyograph	2
	890.1385	Diagnostic electromyograph needle electrode	2
	890.1450	Powered reflex hammer	2
	890.1850	Diagnostic muscle stimulator	2
or (Therapy)	890.5850	Powered muscle stimulator	2
Therapeutic Equipment	890.5100	Immersion hydrobath	2
	890.5110	Paraffin bath	2
	890.5500	Infrared lamp	2
	890.5720	Water circulating hot or cold pack	2
	890.5740	Powered heating pad	2
Radiology Panel			
MRI	892.1000	Magnetic resonance diagnostic device	2
Ultrasound Diagnostic	884.2660	Fetal ultrasonic monitor and accessories	2
	892.1540	Nonfetal ultrasonic monitor	
	892.1560	Ultrasonic pulsed echo imaging system	2
	892.1570	Diagnostic ultrasonic transducer	2
	892.1550	Ultrasonic pulsed doppler imaging system	
Angiographic	892.1600	Angiographic x-ray system	2
Diagnostic X-Ray	892.1610	Diagnostic x-ray beam-limiting device	2
	892.1620	Cine or spot fluorographic x-ray camera	2
	892.1630	Electrostatic x-ray imaging system	2
	892.1650	Image-intensified fluoroscopic x-ray system	2
	892.1670	Spot film device	2
	892.1680	Stationary x-ray system	2
	892.1710	Mammographic x-ray system	2
	892.1720	Mobile x-ray system	2
	892.1740	Tomographic x-ray system	1
	892.1820	Pneumoencephalographic chair	2
	892.1850	Radiographic film cassette	1
	892.1860	Radiographic film/cassette changer	1
	892.1870	Radiographic film/cassette changer programmer	2
	892.1900	Automatic radiographic film processor	2
	892.1980	Radiologic table	1
CT Scanner	892.1750	Computed tomography x-ray system	2
Radiation Therapy	892.5050	Medical charged-particle radiation therapy system	2
	892.5300	Medical neutron radiation therapy system	2
	892.5700	Remote controlled radionuclide applicator system	2
	892.5710	Radiation therapy beam-shaping block	2
	892.5730	Radionuclide brachytherapy source	2
	892.5750	Radionuclide radiation therapy system	2
	892.5770	Powered radiation therapy patient support assembly	2
	892.5840	Radiation therapy simulation system	2
	892.5930	Therapeutic x-ray tube housing assembly	1
Nuclear Medicine	892.1170	Bone densitometer	2
	892.1200	Emission computed tomography system	2

TABLE 3.—MEDICAL DEVICES FOR POSSIBLE INCLUSION IN SCOPE OF PRODUCT COVERAGE DURING OPERATIONAL PERIOD[1]—Continued

Product Family	21 CFR Section No	Device Name	Tier
	892.1310	Nuclear tomography system	1
	892.1390	Radionuclide rebreathing system	2
General/Plastic Surgery Panel			
Surgical Lamps	878.4630	Ultraviolet lamp for dermatologic disorders	2
	890.5500	Infrared lamp	2
	878.4580	Surgical lamp	2
Electrosurgical Cutting Equipment	878.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology	2
	878.4400	Electrosurgical cutting and coagulation device and accessories	2
Miscellaneous	878.4780	Powered suction pump	2

[1]Descriptive information on product codes, panel codes, and other medical device identifiers may be viewed on FDA's Internet Web Site at ''http://www.fda.gov/cdrh/prodcode.html''.

Appendix C of Subpart B [Reserved]

Appendix D of Subpart B [Reserved]

Appendix E of Subpart B [Reserved]

Appendix F of Subpart B [Reserved]

Subpart C—Framework or ''Umbrella'' Provisions

§ 26.60 Definitions.

(a) The following terms and definitions shall apply to this part only:

(1) *Designating Authority* means a body with power to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies as specified under this part.

(2) *Designation* means the identification by a designating authority of a conformity assessment body to perform conformity assessment procedures under this part.

(3) *Regulatory Authority* means a government agency or entity that exercises a legal right to control the use or sale of products within a party's jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.

(b) Other terms concerning conformity assessment used in this part shall have the meaning given elsewhere in this part or in the definitions contained in Guide 2 (1996 edition) of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). In the event of an inconsistency between the ISO/IEC Guide 2 and definitions in this part, the definitions in this part shall prevail. The ISO/IEC Guide 2 is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the International Organization for Standardization, 1, rue de Varembé, Case postale 56, CH–1211 Genève 20, Switzerland, or on the Internet at ''http://www.iso.ch'' or may be examined at the Food and Drug Administration's Medical Library, 5600 Fishers Lane, rm. 11B–40, Rockville, MD 20857, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

§ 26.61 Purpose of this part.

This part specifies the conditions by which each party will accept or recognize results of conformity assessment procedures, produced by the other party's conformity assessment bodies (CAB's) or authorities, in assessing conformity to the importing party's requirements, as specified on a sector-specific basis in subparts A and B of this part, and to provide for other related cooperative activities. The objective of such mutual recognition is to provide effective market access throughout the territories of the parties with regard to conformity assessment for all products covered under this part. If any obstacles to such access arise, consultations will promptly be held. In the absence of a satisfactory outcome of such consultations, the party alleging its market access has been denied, may, within 90 days of such consultation, invoke its right to terminate this part in accordance with § 26.80.

§ 26.62 General obligations.

(a) The United States shall, as specified in subparts A and B of this part, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the United States, produced by the other party's conformity assessment bodies (CAB's) and/or authorities.

(b) The European Community (EC) and its Member States shall, as specified in subparts A and B of this part, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the EC and its Member States, produced by the other party's CAB's and/or authorities.

(c) Where sectoral transition arrangements have been specified in subparts A and B of this part, the above obligations will apply following the successful completion of those sectoral transition arrangements, with the understanding that the conformity assessment procedures utilized assure conformity to the satisfaction of the receiving party, with applicable legislative, regulatory, and administrative provisions of that party, equivalent to the assurance offered by the receiving party's own procedures.

§ 26.63 General coverage of this part.

(a) This part applies to conformity assessment procedures for products and/or processes and to other related cooperative activities as described in this part.

(b) Subparts A and B of this part may include:

(1) A description of the relevant legislative, regulatory, and administrative provisions pertaining to the conformity assessment procedures and technical regulations;

(2) A statement on the product scope and coverage;

(3) A list of designating authorities;

(4) A list of agreed conformity assessment bodies (CAB's) or authorities or a source from which to obtain a list of such bodies or authorities and a statement of the scope of the conformity assessment procedures for which each has been agreed;

(5) The procedures and criteria for designating the CAB's;

(6) A description of the mutual recognition obligations;

(7) A sectoral transition arrangement;

(8) The identity of a sectoral contact point in each party's territory; and

(9) A statement regarding the establishment of a Joint Sectoral Committee.

(c) This part shall not be construed to entail mutual acceptance of standards or technical regulations of the parties and, unless otherwise specified in subpart A or B of this part, shall not entail the mutual recognition of the equivalence of standards or technical regulations.

§ 26.64 Transitional arrangements.

The parties agree to implement the transitional commitments on confidence building as specified in subparts A and B of this part.

(a) The parties agree that each sectoral transitional arrangement shall specify a time period for completion.

(b) The parties may amend any transitional arrangement by mutual agreement.

(c) Passage from the transitional phase to the operational phase shall proceed as specified in subparts A and B of this part, unless either party documents that the conditions provided in such subpart for a successful transition are not met.

§ 26.65 Designating authorities.

The parties shall ensure that the designating authorities specified in subpart B of this part have the power and competence in their respective territories to carry out decisions under this part to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies (CAB's).

§ 26.66 Designation and listing procedures.

The following procedures shall apply with regard to the designation of conformity assessment bodies (CAB's) and the inclusion of such bodies in the list of CAB's in subpart B of this part:

(a) The designating authority identified in subpart B of this part shall designate CAB's in accordance with the procedures and criteria set forth in subpart B of this part;

(b) A party proposing to add a CAB to the list of such bodies in subpart B of this part shall forward its proposal of one or more designated CAB's in writing to the other party with a view to a decision by the Joint Committee;

(c) Within 60 days following receipt of the proposal, the other party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the inclusion in subpart B of this part of the proposed CAB or CAB's shall take effect; and

(d) In the event that the other party contests on the basis of documented evidence the technical competence or compliance of a proposed CAB, or indicates in writing that it requires an additional 30 days to more fully verify such evidence, such CAB shall not be included on the list of CAB's in subpart B of this part. In this instance, the Joint Committee may decide that the body concerned be verified. After the completion of such verification, the proposal to list the CAB in subpart B may be resubmitted to the other party.

§ 26.67 Suspension of listed conformity assessment bodies.

The following procedures shall apply with regard to the suspension of a conformity assessment body (CAB) listed in subpart B of this part.

(a) A party shall notify the other party of its contestation of the technical competence or compliance of a CAB listed in subpart B of this part and the contesting party's intent to suspend such CAB. Such contestation shall be exercised when justified in an objective and reasoned manner in writing to the other party;

(b) The CAB shall be given prompt notice by the other party and an opportunity to present information in order to refute the contestation or to correct the deficiencies which form the basis of the contestation;

(c) Any such contestation shall be discussed between the parties in the Joint Sectoral Committee described in subpart B of this part. If there is no Joint Sectoral Committee, the contesting party shall refer the matter directly to the Joint Committee. If agreement to suspend is reached by the Joint Sectoral Committee or, if there is no Joint Sectoral Committee, by the Joint Committee, the CAB shall be suspended;

(d) Where the Joint Sectoral Committee or Joint Committee decides that verification of technical competence or compliance is required, it shall normally be carried out in a timely manner by the party in whose territory the body in question is located, but may be carried out jointly by the parties in justified cases;

(e) If the matter has not been resolved by the Joint Sectoral Committee within 10 days of the notice of contestation, the matter shall be referred to the Joint Committee for a decision. If there is no Joint Sectoral Committee, the matter shall be referred directly to the Joint Committee. If no decision is reached by the Joint Committee within 10 days of the referral to it, the CAB shall be suspended upon the request of the contesting party;

(f) Upon the suspension of a CAB listed in subpart B of this part, a party is no longer obligated to accept or recognize the results of conformity assessment procedures performed by that CAB subsequent to suspension. A party shall continue to accept the results of conformity assessment procedures performed by that CAB prior to suspension, unless a regulatory authority of the party decides otherwise based on health, safety or environmental considerations or failure to satisfy other requirements within the scope of subpart B of this part; and

(g) The suspension shall remain in effect until agreement has been reached by the parties upon the future status of that body.

§ 26.68 Withdrawal of listed conformity assessment bodies.

The following procedures shall apply with regard to the withdrawal from subpart B of this part of a conformity assessment body (CAB):

(a) A party proposing to withdraw a CAB listed in subpart B of this part shall forward its proposal in writing to the other party;

(b) Such CAB shall be promptly notified by the other party and shall be provided a period of at least 30 days from receipt to provide information in order to refute or to correct the deficiencies which form the basis of the proposed withdrawal;

(c) Within 60 days following receipt of the proposal, the other party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the withdrawal from the list in subpart B of this part of the CAB shall take effect;

(d) In the event the other party opposes the proposal to withdraw by supporting the technical competence and compliance of the CAB, the CAB shall not at that time be withdrawn from the list of CAB's in subpart B of this part. In this instance, the Joint Sectoral Committee or the Joint Committee may decide to carry out a joint verification of the body concerned. After the completion of such verification, the proposal for withdrawal of the CAB may be resubmitted to the other party; and

(e) Subsequent to the withdrawal of a CAB listed in subpart B of this part, a party shall continue to accept the results of conformity assessment procedures performed by that CAB prior to withdrawal, unless a regulatory authority of the party decides otherwise based on health, safety, and environmental considerations or failure to satisfy other requirements within the scope of subpart B of this part.

§ 26.69 Monitoring of conformity assessment bodies.

The following shall apply with regard to the monitoring of conformity assessment bodies (CAB's) listed in subpart B of this part:

(a) Designating authorities shall assure that their CAB's listed in subpart B of this part are capable and remain capable of properly assessing conformity of products or processes, as applicable, and as covered in subpart B of this part. In this regard, designating authorities shall maintain, or cause to maintain, ongoing surveillance over their CAB's by means of regular audit or assessment;

(b) The parties undertake to compare methods used to verify that the CAB's listed in subpart B of this part comply with the relevant requirements of subpart B of this part. Existing systems for the evaluation of CAB's may be used as part of such comparison procedures;

(c) Designating authorities shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures. With the consent of both parties, this consultation may include joint participation in audits/inspections related to conformity assessment activities or other assessments of CAB's listed in subpart B of this part; and

(d) Designating authorities shall consult, as necessary, with the relevant regulatory authorities of the other party to ensure that all technical requirements are identified and are satisfactorily addressed.

§ 26.70 Conformity assessment bodies.

Each party recognizes that the conformity assessment bodies (CAB's) listed in subpart B of this part fulfill the conditions of eligibility to assess conformity in relation to its requirements as specified in subpart B of this part. The parties shall specify the scope of the conformity assessment procedures for which such bodies are listed.

§ 26.71 Exchange of information.

(a) The parties shall exchange information concerning the implementation of the legislative, regulatory, and administrative provisions identified in subparts A and B of this part.

(b) Each party shall notify the other party of legislative, regulatory, and administrative changes related to the subject matter of this part at least 60 days before their entry into force. Where considerations of safety, health or environmental protection require more urgent action, a party shall notify the other party as soon as practicable.

(c) Each party shall promptly notify the other party of any changes to its designating authorities and/or conformity assessment bodies (CAB's).

(d) The parties shall exchange information concerning the procedures used to ensure that the listed CAB's under their responsibility comply with the legislative, regulatory, and administrative provisions outlined in subpart B of this part.

(e) Regulatory authorities identified in subparts A and B of this part shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures and to ensure that all technical requirements are identified and are satisfactorily addressed.

§ 26.72 Sectoral contact points.

Each party shall appoint and confirm in writing contact points to be responsible for activities under subparts A and B of this part.

§ 26.73 Joint Committee.

(a) A Joint Committee consisting of representatives of the United States and the European Community (EC) will be established. The Joint Committee shall be responsible for the effective functioning of this part.

(b) The Joint Committee may establish Joint Sectoral Committees comprised of appropriate regulatory authorities and others deemed necessary.

(c) The United States and the EC shall have one vote in the Joint Committee. The Joint Committee shall make its decisions by unanimous consent. The Joint Committee shall determine its own rules and procedures.

(d) The Joint Committee may consider any matter relating to the effective functioning of this part. In particular it shall be responsible for:

(1) Listing, suspension, withdrawal and verification of conformity assessment bodies (CAB's) in accordance with this subpart and subpart B of this part;

(2) Amending transitional arrangements in subparts A and B of this part;

(3) Resolving any questions relating to the application of this part not otherwise resolved in the respective Joint Sectoral Committees;

(4) Providing a forum for discussion of issues that may arise concerning the implementation of this part;

(5) Considering ways to enhance the operation of this part;

(6) Coordinating the negotiation of additional subparts; and

(7) Considering whether to amend this part in accordance with § 26.80.

(e) When a party introduces new or additional conformity assessment procedures affecting subpart A or B of this part, the parties shall discuss the matter in the Joint Committee with a view to bringing such new or additional procedures within the scope of this part, where relevant.

§ 26.74 Preservation of regulatory authority.

(a) Nothing in this part shall be construed to limit the authority of a party to determine, through its legislative, regulatory, and administrative measures, the level of protection it considers appropriate for safety; for protection of human, animal, or plant life or health; for the environment; for consumers; and otherwise with regard to risks within the scope of the applicable subpart A or B of this part.

(b) Nothing in this part shall be construed to limit the authority of a regulatory authority to take all appropriate and immediate measures whenever it ascertains that a product may:

(1) Compromise the health or safety of persons in its territory;

(2) Not meet the legislative, regulatory, or administrative provisions within the scope of the applicable subpart A or B of this part; or

(3) Otherwise fail to satisfy a requirement within the scope of the applicable subpart A or B of this part. Such measures may include withdrawing the products from the market, prohibiting their placement on the market, restricting their free movement, initiating a product recall, and preventing the recurrence of such problems, including through a prohibition on imports. If the regulatory authority takes such action, it shall inform its counterpart authority and the other party within 15 days of taking such action, providing its reasons.

§ 26.75 Suspension of recognition obligations.

Either party may suspend its obligations under subpart A or B of this part, in whole or in part, if:

(a) A party suffers a loss of market access for the party's products within the scope of subpart A or B of this part as a result of the failure of the other party to fulfill its obligations under this part;

(b) The adoption of new or additional conformity assessment requirements as referenced in § 26.73(e) results in a loss of market access for the party's products within the scope of subpart B of this part because conformity assessment bodies (CAB's) designated by the party in order to meet such requirements have not been recognized by the party implementing the requirements; or

(c) The other party fails to maintain legal and regulatory authorities capable of implementing the provisions of this part.

§ 26.76 Confidentiality.

(a) Each party agrees to maintain, to the extent required under its laws, the confidentiality of information exchanged under this part.

(b) In particular, neither party shall disclose to the public, nor permit a conformity assessment body (CAB) to disclose to the public, information exchanged under this part that constitutes trade secrets, confidential commercial or financial information, or information that relates to an ongoing investigation.

(c) A party or a CAB may, upon exchanging information with the other party or with a CAB of the other party, designate the portions of the information that it considers to be exempt from disclosure.

(d) Each party shall take all precautions reasonably necessary to protect information exchanged under this part from unauthorized disclosure.

§ 26.77 Fees.

Each party shall endeavor to ensure that fees imposed for services under this part shall be commensurate with the services provided. Each party shall ensure that, for the sectors and conformity assessment procedures covered under this part, it shall charge no fees with respect to conformity assessment services provided by the other party.

§ 26.78 Agreements with other countries.

Except where there is written agreement between the parties, obligations contained in mutual recognition agreements concluded by either party with a party not a party to this part (a third party) shall have no force and effect with regard to the other party in terms of acceptance of the results of conformity assessment procedures in the third party.

§ 26.79 Territorial application.

This part shall apply, on the one hand, to the territories in which the Treaty establishing the European Community (EC) is applied, and under the conditions laid down in that Treaty and, on the other hand, to the territory of the United States.

§ 26.80 Entry into force, amendment and termination.

(a) The ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived, including its sectoral annexes on telecommunications equipment, electromagnetic compatibility, electrical safety, recreational craft, pharmaceutical GMP inspections, and medical devices shall enter into force on the first day of the second month following the date on which the parties have exchanged letters confirming the completion of their respective procedures for the entry into force of that agreement.

(b) That agreement including any sectoral annex may, through the Joint Committee, be amended in writing by the parties to that agreement. Those parties may add a sectoral annex upon the exchange of letters. Such annex shall enter into force 30 days following the date on which those parties have exchanged letters confirming the completion of their respective procedures for the entry into force of the sectoral annex.

(c) Either party to that agreement may terminate that agreement in its entirety or any individual sectoral annex thereof by giving the other party to that agreement 6 months notice in writing. In the case of termination of one or more sectoral annexes, the parties to that agreement will seek to achieve by consensus to amend that agreement, with a view to preserving the remaining Sectoral Annexes, in accordance with the procedures in this section. Failing such consensus, that agreement shall terminate at the end of 6 months.

(d) Following termination of that agreement in its entirety or any individual sectoral annex thereof, a party to that agreement shall continue to accept the results of conformity assessment procedures performed by conformity assessment bodies under that agreement prior to termination, unless a regulatory authority in the party decides otherwise based on health, safety and environmental considerations or failure to satisfy other requirements within the scope of the applicable sectoral annex.

§ 26.81 Final provisions.

(a) The sectoral annexes referred to in § 26.80(a), as well as any new sectoral annexes added pursuant to § 26.80(b), shall form an integral part of the ''Agreement on Mutual Recognition Between the United States of America and the European Community,'' from which this part is derived.

(b) For a given product or sector, the provisions contained in subparts A and B of this part shall apply in the first place, and the provisions of subpart C of this part in addition to those provisions. In the case of any inconsistency between the provisions of subpart A or B of this part and subpart C of this part, subpart A or B shall prevail, to the extent of that inconsistency.

(c) The agreement from which this part is derived shall not affect the rights and obligations of the parties under any other international agreement.

(d) In the case of subpart B of this part, the parties shall review the status of such subpart at the end of 3 years from entry into force of subpart B.

Dated: April 6, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

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DEPARTMENT OF JUSTICE

Parole Commission

28 CFR Part 2

Paroling, Recommitting, and Supervising Federal Prisoners: Prisoners Serving Sentences Under the District of Columbia Code

AGENCY: United States Parole Commission, Justice.

ACTION: Proposed rule.

SUMMARY: The U.S. Parole Commission is proposing to incorporate into the Code of Federal Regulations, in amended and supplemented form, the regulations of the District of Columbia that govern the paroling authority that will be assumed by the U.S. Parole Commission on August 5, 1998. The paroling authority of the District of Columbia Board of Parole will be transferred to the U.S. Parole Commission under the National Capital Revitalization and Self-Government Improvement Act of 1997, which permits the Commission to amend and supplement the District's parole regulations pursuant to federal rulemaking procedures.

DATES: Comments must be received by June 9, 1998.

ADDRESSES: Send comments to Office of General Counsel, U.S. Parole Commission, 5550 Friendship Blvd., Chevy Chase, Maryland 20815.

FOR FURTHER INFORMATION CONTACT: Pamela A. Posch, Office of General Counsel, U.S. Parole Commission, 5550 Friendship Blvd., Chevy Chase, Maryland 20815, telephone (301) 492–5959.

SUPPLEMENTARY INFORMATION: Under Section 11231 of the National Capital Revitalization and Self-Government Improvement Act of 1997 (Pub. L. 105–33) the U.S. Parole Commission is required, not later than August 5, 1998,