

**SECOND JOINT STATUS REPORT ON THE U.S.-JAPAN ENHANCED INITIATIVE  
ON DEREGULATION AND COMPETITION POLICY  
May 3, 1999**

On May 15, 1998, the Governments of the United States and Japan issued the First Joint Status Report on the U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy (First Joint Report) under the U.S.-Japan Framework for a New Economic Partnership. Based on the reaffirmation of the two governments in the First Joint Report of their determination to further promote deregulation, they have continued to devote substantial resources to the implementation of the Enhanced Initiative on Deregulation and Competition Policy (Enhanced Initiative), recognizing the importance of actively promoting deregulation and applying an effective competition policy.

The Governments of the United States and of Japan have held meetings of the High-level Officials Group and of six Expert-level groups (telecommunications, housing, medical devices and pharmaceuticals, financial services, energy, and structural issues, including competition policy, distribution, and issues related to transparency and government practices) during the second year of the Enhanced Initiative on Deregulation and Competition Policy. Consistent with the principles of two-way dialogue and the aim of the achievement of tangible progress, both sides have exchanged views and interests on a wide variety of deregulation items. As part of that effort, the Government of the United States provided a submission to the Government of Japan in October 1998. The Government of Japan also provided a submission to the Government of the United States in October 1998.

The Government of Japan has taken a series of deregulatory measures, the latest and the most significant being the adoption on March 30, 1999 of revisions to its three-year program for the promotion of deregulation. The salient Japanese deregulatory and other measures that relate to the dialogue under the Enhanced Initiative are set out in this Report. This Report also contains a series of U.S. deregulatory measures. Both governments welcomed the progress that has been achieved under the Enhanced Initiative over the past year, and encouraged continued efforts to address outstanding proposals for deregulation. The Governments of the United States and Japan share the view that these measures will improve market access for competitive goods and services, enhance consumers' interests, increase efficiency and promote economic activity. Consistent with international obligations, the measures undertaken under the Enhanced Initiative will provide nondiscriminatory treatment to competitive foreign goods and services.

Both governments reaffirm their determination to further promote deregulation and to continue dialogue under the Enhanced Initiative, including considering new issues. Under the Enhanced Initiative, the two governments, upon the request of either government, will meet at a mutually convenient time to address these measures, and will work closely together to ensure that these measures contribute to fulfilling the objective of the Enhanced Initiative.

**DEREGULATION AND OTHER MEASURES BY THE GOVERNMENT OF JAPAN  
UNDER THE ENHANCED INITIATIVE**

**A. TELECOMMUNICATIONS**

**1. Interconnection**

**(1) Reduction of Interconnection Rates**

- (a) NTT's interconnection rates are calculated based on "The Interconnection Accounting Rules for Designated Telecommunications Facilities" and "The Interconnection Cost Calculating Rules on the Interconnection Rates for Designated Telecommunications Facilities," both of which are ordinances of the Ministry of Posts and Telecommunications (MPT). NTT's interconnection rates for FY 1998 were approved on January 22, 1999, based on these rules, resulting in reduction of rates.
- (b) Interconnection rates for FY 1999 will, after clarification of the accounting results for FY 1998 on which calculations will be based, be changed by the revisions of NTT's Articles of Agreement concerning interconnection. MPT will ensure that under this new accounting system only costs associated with interconnection will be used to calculate interconnection rates. In this process, the Government of Japan will continue its policy of promoting reductions of the interconnection rates as much as possible, within the scope of its existing authority.
- (c) In deciding whether to approve NTT's FY 1999 tariff, MPT will ensure that the relationship between retail rates and interconnection rates does not impair local competition.
- (d) NTT will be required, in accordance with its FY 1999 edition of Articles of Agreement concerning interconnection, to make any resulting reductions in its interconnection rates effective from the beginning of FY 1999.

**(2) Interconnection with NTT DoCoMo**

- (a) MPT confirms that access to NTT DoCoMo's facilities falls under the interconnection obligations imposed on Type 1 carriers, and in considering approval of an interconnection agreement, MPT will, in accordance with the Telecommunications Business Law, examine to ensure that NTT DoCoMo's interconnection rates are cost-oriented and non-discriminatory. In addition, MPT will arbitrate disputes concerning such access based on these same principles.

- (b) MPT will examine the method of introducing fair and transparent interconnection, in case measures need to be taken to facilitate interconnection between NTT DoCoMo and other carriers, in FY 2000. In the course of MPT's review of the interconnection regime in FY 2000, MPT will determine whether to categorize NTT DoCoMo as a "designated carrier".
- (3) **Streamlining Interconnection Agreements:** The final report of "The Study Group on Streamlining Interconnection Agreements" was released in March, 1999. Carriers can streamline their interconnection agreements among more than two carriers referring to the measures presented in the report. MPT will not prevent the use of clearing houses which provide services on a non-discriminatory, cost-based basis.
- (4) **Access to Cable landing Stations:** MPT confirms that it will arbitrate, in accordance with the Telecommunications Business Law, any dispute relating to access to international cable landing stations through interconnection arrangements, including those involving co-locations of equipment in their facilities.
- (5) **Number Portability:** The final report of "The Study Group on Cost-Sharing of Number Portability" was announced in March 1999. Local number portability will be introduced, based on the report, as early as possible around FY 2000.
- (6) **Dialing Parity:** The final report of "The Study Group on Dialing Parity" was released in November 1998. Based on the report, Dialing Parity will be introduced around FY 2000.

## 2. Network Flexibility

- (1) MPT confirms that the Telecommunications Business Law provides Type 1 carriers three arrangements for building out part of their networks using transmission line facilities owned by other Type 1 carriers: consignment, IRU, and interconnection. MPT recognizes Type 1 carriers' needs for flexibility in choosing, consistent with the Telecommunications Business Law, which of such arrangements to utilize, based on the Type 1 carriers' evaluation of their practical and economic requirements, and the technical viability of such arrangements.
- (2) MPT will make publicly available, by the end of CY 1999, materials that facilitate understanding of the possibilities for utilization of such arrangements. The materials include explanations of laws, orders and examination standards, and examples of arrangements already permitted. MPT will update these materials annually to reflect evolving business needs and technical developments.

### 3. **Rights of Way**

- (1) The Government of Japan surveyed the existing circumstance on the procedures to use available properties (such as land and facility) for laying of cables, and released the results of the study on December 25, 1998. In line with the results of the study, the government published the results of its research of the measures for improvement taken by the entities concerned on March 26, 1999.
  - (2) The Government of Japan will receive complaints with regard to laying of cables, look into the matters needed within the scope of available cooperation from related entities and then reply to the complaint of applicants in the form of appropriately compiled results. The cases will be regarded as references for the consideration of further improvement in the review during FY 1999.
  - (3) It is necessary to conduct further study in the future, considering how the proposed measures will work and listening to a broad range of views. In FY 1999, a review will be conducted with participation of the Ministries concerned.
  - (4) In FY 1999, the Government of Japan will continue to make efforts to facilitate laying of cables by telecommunications carriers and cable television operators. In this connection, the review group will closely monitor implementation of the measures for improvement, evaluate their effectiveness in improving access to rights-of-way, consider complaints, opinions and questions from domestic and foreign entities, and review the need for other means of improving access to rights-of-way.
4. **Power Main Signaling:** MPT has initiated a study reviewing technical requirements for power main signaling devices on the base of the technical data which are necessary for the study. After completing the study, MPT will complete a draft of proposed necessary regulatory changes by mid-1999 to expand the scope of permissible power main signaling devices, and, applying the Public Comment Procedure, will issue necessary regulations as soon as possible.
  5. **KDD Foreign Investment Restrictions:** The Government of Japan eliminated foreign investment restrictions in KDD.
  6. **Foreign Investment Restrictions on Cable TV Businesses:** The Government of Japan submitted a bill in March 1999 to remove restrictions on foreign investment and on foreign board membership for cable television operators to the ordinary session of the Diet in the Spring of 1999.
  7. **Testing and Certification: Reduction of Fees:** The Type Certification System was established by "The Law on Modification of the Related Laws to Rationalize the

Regulations in the Telecommunications Area” (passed on April 30 and promulgated on May 8, 1998; entered into effect on March 6, 1999), which amends the Radio Law. MPT dramatically reduced the fee charged and shortened the processing period on March 8, 1999. Furthermore, a system was also established whereby Japan accepts certifications provided by foreign conformity assessment bodies recognized by the Minister of Posts and Telecommunications, whether or not a Mutual Recognition Agreement exists. It is the first time that such a system for acceptance or recognition of certifications regarding technical regulations of Japan has been introduced.

8. **Public Comment Procedures:** MPT will continue to use public comment procedures for major regulatory changes.
9. **100 Destination Rule (Eliminating Restrictions on International Transit Arrangements):** Regarding international traffic routing by Type I telecommunications carriers providing international telecommunications services, restrictions on third country traffic routing in cases where the number of destinations is no more than 100 was abolished in June 1998.
10. **Cable TV Issues:** MPT will ensure that NTT does not impose unreasonable or anti-competitive conditions on the use of its fiber in accordance with Article 31-4 of the Telecommunications Business Law.
11. **DSL (Digital Subscriber Lines):** MPT amended its ordinance regarding the technical standards of leakage on January 7, 1999, so that all telecommunications carriers can provide x-DSL service. After this amendment, one carrier began providing x-DSL service from February 1999.

## **B. HOUSING**

### **1. Progress in FY 1998**

- (1) The Government of Japan amended the Building Standards Law (BSL) on June 5, 1998 to introduce performance-based codes, a uniform evaluation system for new building materials by June 2000 and upgraded and efficient building confirmation and inspection procedures, including an interim inspection system, as of May 1, 1999. The Law will be fully implemented by June 2000.
- (2) Japan initiated a process to coordinate funding for the translation into English of the amended BSL and related documents, e.g., enforcement orders and notifications, and provided information on their implementation through a series of formal and informal meetings.

- (3) Japan held, with the United States, a series of joint seminars, beginning on July 2, 1998, to introduce and promote procedures for approval of three-story, multi-family, wood housing and certain commercial and mixed-use wood buildings in quasi-fire protection districts, which was permitted beginning in August 1997.
- (4) Testing methods and procedures for 2x4 construction were established and published in December 1998, based on international and North American practice.
- (5) American Lumber Standards Committee (ALSC) and Western Wood Products Association (WWPA) grademarks received recognition as 2x4 construction material for Machine Stress-Rated Lumber (MSR) in February 1998, and for Finger-Jointed Lumber (FJ) in June 1998.
- (6) An engineer training program was concluded in 1998 required for recognition of the Underwriters Laboratories as a fire-testing laboratory for various fire preventive building materials.
- (7) Japan concluded that the cordless nailer (IM350/90CTQ) did not fall within the definition of “firearms” in the Firearms and Swords Control Law in March 1998.
- (8) Japan continued ongoing dialogue with the United States in the Housing Experts Group and the Building Experts Committee on recognition of U.S. nails and nailing systems.
- (9) Japan continued ongoing dialogue with the United States in the Housing Experts Group and other fora on market access and standards-related issues in the housing sector.

## 2. **New Developments**

- (1) Upon its introduction by the GOJ on April 1, 1999, the Ministry of Construction (MOC) will apply the Public Comment Procedure in developing cabinet orders, ministerial ordinances, notifications and other relevant regulations that will be issued to implement revisions to the BSL.
- (2) By May 1, 1999, MOC will develop and implement all measures necessary for the use of performance-based building standards for three-story, multi-family wood housing and certain commercial and mixed-use wood buildings in quasi-fire protection districts.
- (3) Japan and the United States will expand the scope and frequency of joint educational programs to acquaint Japanese builders and consumers with newly made available, U.S.-style building materials and methods.

- (4) By June 1999, MOC will issue and implement guidelines, which will include information on the content and timing of inspections, on new interim inspection systems for building code enforcement.
- (5) Within six months of submission of all necessary data from the United States, MOC will authorize the use of U.S. power-driven nails and staples in Japan.
- (6) MOC will accredit Underwriters Laboratory as a testing laboratory for fire-preventive building materials by recognizing certain necessary protocols after conducting an on-site examination.
- (7) The Ministry of Agriculture, Forestry and Fisheries (MAFF) will revise Japanese Agricultural Standards (JAS) for structural plywood during an early stage of FY 1999, with increased emphasis on performance-based standards, including board strength.
- (8) Within two months of the submission of requested data from the United States, which is anticipated by September 1, 1999, the MOC will re-evaluate the existing correction factors of Oriented Strand Board (OSB) with a view to applying the existing plywood correction factors to OSB, thereby achieving equivalency.
- (9) By June 1, 1999, the MOC will publicly reiterate that it does not intend for its programs to discriminate against imported products.
- (10) By June 2000, the Government of Japan will establish and implement a system of recognized/designated evaluation bodies for the nationwide acceptance and evaluation of test data for building methods and materials, and will facilitate implementation by providing opportunities for discussions with potential applicants prior to this date.
- (11) A bill amending the JAS Law will be presented to the Diet during the present session with a view to bestowing on testing organizations overseas a function as JAS-registered grading organizations (RGO) and/or JAS-registered certification organizations (RCO).
- (12) The MOC will provide the information requested by the United States concerning the approval process for aluminum fire-resistant windows in 1991.

## **C. MEDICAL DEVICES AND PHARMACEUTICALS**

### **1. Recognition of Innovation**

Recognize the value of innovation of pharmaceuticals and medical devices, so as not to impede the introduction of innovative products which bring more effective and more cost-effective treatments to patients.

- (1) When revising the National Health Insurance Pharmaceutical Pricing System, within the circumstances of the National Health Insurance System in Japan, the Government of Japan recognizes the value of innovation of pharmaceuticals so as not to impede or prevent the introduction of innovative pharmaceuticals which bring more effective and more cost-effective treatments to patients, and continues to study the pharmaceutical pricing system with related parties, including the U.S. industry, recognizing the role of the market.
- (2) Streamlined and transparent procedures will be developed as soon as possible for the prompt creation of new by-function reimbursement categories for new medical devices within a specified period of time, taking into consideration the views of interested parties, subject to the approval of Chuikyo. The Government of Japan will work both to develop such procedures as well as to institute restructured categories and a by-function system for pacemakers, and will work to implement these measures simultaneously within FY 2000.

## 2. **Acceptance of Foreign Clinical Data**

- (1) The Ministry of Health and Welfare (MHW) directive issued in August 1998, based on the International Conference on Harmonization (ICH) guidelines, expanded the acceptance of foreign clinical test data for the approval of new pharmaceuticals.
- (2) To further promote deregulation in this sector, the Government of Japan will:
  - (a) Accept foreign clinical test data for the approval of new medical devices and pharmaceuticals that meet, or are equivalent to, Japanese Good Clinical Practice (GCP) standards or ICH GCP;
  - (b) On April 1, 2000, revoke the requirement that clinical data submitted with an application for medical device or pharmaceutical approval must be presented at a domestic conference of specialists or published in an academic journal, and in the interim treat publication or presentation of such data as optional; and
  - (c) Noting that the data requirements of the reimbursement process for medical devices can be different from those of the approval process, make efforts not to impose an unnecessary or redundant burden on applicants when requesting submission of data, including clinical data. The



Government of Japan will make efforts so as not to impose an unnecessary or redundant burden on applicants, including the possibility of utilizing foreign clinical data on an individual basis, and to work to implement such measures as soon as possible, but not later than within FY 2000, including clarifying in writing clearly from the beginning of and/or as necessary throughout the process what information is necessary to apply for reimbursement, including the scope of foreign clinical data that can be used. These measures are subject to the approval of Chuikyo, and MHW will work with Chuikyo as it considers approval of the above steps. The Government of Japan will also continue to respond appropriately to applicants' consultations before and during applying for reimbursement. This matter will be discussed further as necessary.

### 3. **Approval Process**

- (1) As soon as possible, but no later than April 1, 2000, the Government of Japan will ensure that decisions made by review personnel in the approval processes for medical devices and pharmaceuticals be treated as binding commitments by reviewing institutions and are binding on other reviewers throughout the process by, for example, requiring that evaluation standards, requests for information, questions and all other types of inquiries be set out in writing.
- (2) The consistency and speed of the approval process for medical devices will be improved. Effective review by the Pharmaceutical and Medical Devices Evaluation Center and the Japan Association for the Advancement for Medical Equipment in the approval process will be promoted, for example, by clarifying the criteria of partial change, and criteria to distinguish "me-too medical devices" from "new devices" which require clinical test data, and allowing for continual direct communication between reviewing bodies and the applicant. Necessary measures have begun and continuous progress will take place with the first goal of completing such measures for pacemakers and orthopedic implants (bones and joints) by April 1, 2000. The progress of other items will continue to be discussed in the MOSS.
- (3) MHW will make efforts for the proper management of the Highly Advanced Medical Technologies System, such as prompt and transparent procedures, with an eye to ensuring factors, including access to new technologies, subject to the approval of Chuikyo.
- (4) To ensure a smooth transition to the new Japanese GCP, recognition of new drug approval applications and other required documentation such as all clinical data compiled under the old Japanese GCP, or equivalent standards, in clinical trials

begun before April 1, 1997 will be accepted without the need to conduct new clinical trials.

- (5) The approval processing period for new drug applications will be shortened to 12 months by April 2000, with steady and continuous improvement between now and then, and to further speed the introduction of innovative new pharmaceuticals, the approval period will be significantly shortened, particularly for priority drugs. The criteria and the selection review process for approval of applications for priority review treatment have been outlined by MHW notification. To ensure smooth and expeditious NDA (New Drug Application) approvals, the Government of Japan will:
    - (a) Approve dosage strengths which are bracketed by previously approved dosage strengths without having to request further clinical “test” data other than bioequivalency data;
    - (b) On April 1, 2000, abolish the Sub-Committees of the Central Pharmaceutical Affairs Council and institute a team-review system in the Pharmaceutical and Medical Devices Evaluation Center that will allow for continuous direct communication between the reviewers and the applicant. If necessary, applicants may have opportunities to discuss their NDAs with senior MHW officials;
    - (c) From April 1, 2000, the Special Committee on Drugs of the Central Pharmaceutical Affairs Council will meet more frequently than the current quarterly schedule; and
    - (d) In FY 1999, draft and implement Good Reviewer Practice guidelines.
  - (6) From April 1, 1999, a soft contact lenses grouping system has been introduced regarding the testing comparability between chemical disinfectant solutions and soft contact lenses, which will enable a manufacturer to obtain MHW approvals for use of all brands of contact lenses in a group by testing one representative in the group.
4. **Distribution System:** The Government of Japan recognizes that a model contract to be used by manufacturers and wholesalers of medical devices in order to itemize service is developed by an industry association as a voluntary option. The Government of Japan will not endorse or make this model contract as an obligation.
  5. **Transparency**

- (1) With a view to ensuring transparency in the consideration of health care policies, foreign pharmaceutical and medical device manufacturers have been provided, upon request, with meaningful opportunities to state their opinions in the relevant Councils and relevant study groups on an equal basis with Japanese manufacturers, and to exchange views with MHW officials at all levels. MHW will continue to provide such meaningful opportunities.
  - (2) MHW will use the Public Comment Procedure for cabinet orders, ministerial ordinances, guidelines, notifications and any other administrative measures, which are subject to the Procedure as adopted by the Government of Japan on March 23.
6. **Nutritional Supplements:** Based on the conclusion of the task force for discussing the treatment of so called nutritional supplements, which is scheduled to conclude by April 1, 2000, while providing industry and interested parties meaningful opportunities to express their views, the Government of Japan to the greatest extent possible will institutionalize and implement the measures recommended by the Office of the Trade and Investment Ombudsman on March 18, 1996 to promote liberalization of the Japanese nutritional supplements market, for example, vitamins, herbs, and minerals. The status and treatment of nonactive ingredients or excipients will be discussed in view of their use in nutritional supplement products.

#### **D. FINANCIAL SERVICES**

The Japanese financial system reform program (the so-called Japanese "Big Bang"), which was started at the initiative of former Prime Minister Hashimoto in November 1996, aims at revitalizing the Japanese financial markets through fundamental financial liberalization and deregulation based upon the principles of "Free, Fair, and Global." The Financial System Reform Law, which incorporates most of the measures in the reform, went into effect on December 1, 1998. The Government of the United States welcomes this progress.

The following measures have already been implemented since the Birmingham Summit of 1998:

1. Enhanced disclosure by financial institutions to market participants, such as adoption of disclosure standards for non-performing loans similar to those of the U.S. Securities and Exchange Commission (phased in from the business year beginning on and after April 1, 1997);
2. Abolition of the obligation for member insurers to use premium rates calculated by the rating organizations (July 1, 1998);
3. Promoting transaction of assets through establishing a system for securitization of assets via special purpose companies (SPC's) (September 1, 1998);

4. Introduction of new investment trust products (i.e., company-type investment trusts and privately-placed investment trusts) (December 1, 1998);
5. Full liberalization of securities derivatives (December 1, 1998);
6. Elimination of restrictions on the scope of business activities for securities companies (December 1, 1998);
7. Switch from a licensing system to a registration system for securities companies (December 1, 1998);
8. Introduction of proprietary trading systems (December 1, 1998);
9. Improvement of fair trading rules in the Securities and Exchange Law (December 1, 1998);
10. Expansion of the scope of the business activities for banks (lifting the ban on sales of investment trusts, etc.) (December 1, 1998);
11. Expansion of the scope of bank's subsidiaries to all financial related services (December 1, 1998);
12. Creation of the Securities Investor Protection Funds and the Policy Holder Protection Corporations (December 1, 1998);
13. Allowing investment trust management companies and investment advisory companies to grant discretionary authority to other fund management companies (December 1, 1998);
14. Strict separation of customer and proprietary accounts of securities companies (April 1, 1999);
15. Implementation of Public Comment Procedure for making, amending or repealing regulations related to financial services (April 1, 1999);
16. Enhancement of the disclosure such as shift to the framework of the disclosure primarily based on consolidated accounting (phased in from the business year beginning on and after April 1, 1998); and
17. Modification of the provisions to allow fund sponsors to directly transfer the securities when shifting business from trust bank to trust bank for Employee Pension Funds (*kosei nenkin kikin*) and National Pension Funds (*kokumin nenkin kikin*), and from any asset manager to another for Tax-Qualified Plans (*tekikaku taishoku nenkin*) (April 1, 1999).

In addition, the Japanese financial system reform has been proceeding towards its completion by the year 2001 and the following measures are intended to be implemented on the designated schedule:

18. Elimination of restrictions on financial company (nonbank) use of proceeds from bond and Commercial paper issuance (expected to be implemented in May 1999);
19. Elimination of restrictions on the scope of business activities for securities operating subsidiaries of banks and trust banks and trust bank operating subsidiaries of banks and securities companies (scheduled to be implemented on October 1, 1999);
20. Full liberalization of brokerage commissions (scheduled to be implemented on October 1, 1999);
21. Entry of the insurance companies into the banking business (scheduled to be implemented on October 1, 1999), and entry of banks into the insurance business as the completion of mutual entry between the insurance business and other financial business areas (scheduled to be implemented by March 2001);
22. Modification of the provisions concerning Employee Pension Funds (*kosei nenkin kikin*) and National Pension Funds (*kokumin nenkin kikin*) to allow the fund sponsors to directly transfer the securities when shifting business from any asset manager, including investment advisory companies to another (subject to approval by the Diet of the Pension Bills which are being considered for submission to the current session of the Diet); and
23. Modifications of the provisions concerning management of the successor fund for Nempuku to allow the fund sponsors to directly transfer the securities when shifting business from any asset manager, including investment advisory companies to another, and introduction of a new trust scheme (*tokutei shintaku*) as an alternative to the limited partnership scheme for the management of the successor fund for Nempuku, on condition that the successor fund for Nempuku establishes a sufficient risk management system. (Subject to approval by the Diet of pension asset management legislation, and legislation creating a successor institution to *Nempuku*.)

## **E. ENERGY**

### **1. High Pressure Gas Safety Law:**

- (1) The Government of Japan, for compressors and other equipment covered by the High Pressure Gas Safety Law, will accept the American Society of Mechanical Engineers (ASME) standard Section VIII, Division I, UG-101(n)(1998), equivalent of the stress measurement test in lieu of the casing pressure test at four times design pressure.

- (2) Under the High Pressure Gas Safety Law, Japan simplified the application requirements in March 1998, eliminating requirements to append strength calculation sheets to the application when test certifications and other related certifications are provided. The Government of Japan will help U.S. and other foreign companies, as needed, to answer questions regarding implementation of the streamlined application process for the export of compressors and other equipment to Japan that is covered by the High Pressure Gas Safety Law.
2. **Electric Utility Industry Law:** The Government of Japan has submitted a bill to amend the Electric Utility Industry Law, which is to be implemented in July 2000, with the intention of taking the following measures:
  - (1) Adopt performance-based standards for welding for power facilities covered by the Electric Utility Industry Law; and
  - (2) Adopt self-inspection for standards conformity and require those who install the electrical equipment at power facilities, except nuclear power plants, rather than the manufacturer, to conduct the inspection.
3. **Upgrading Existing Power Generation Facilities:** The Government of Japan has submitted a bill to amend the Electric Utility Industry Law, which is to be implemented in July 2000, to shift from a permit and approval system to a notification system for construction or upgrading of all power generating facilities, except nuclear power plants.
4. **Certification of Standby Generator Sets:** The Government of Japan:
  - (1) Will conclude its study of the differences between ISO 8528 and Japan's Fire Prevention Ordinance and, with due consideration to safety concerns, harmonize the Japanese standard with the ISO standard to the extent possible by the end of FY 2000; and
  - (2) Welcomes the decision in August 1998 by the Nippon Electric Generating Association, consistent with the concerns outlined in the 1998 Japan Fair Trade Commission report, to revise and streamline its certification procedures for standby generator sets.
5. **Gasoline Stations and Gasoline Pumps:** The Government of Japan will:
  - (1) Conclude review by the end of FY 1999 of the requirements for hazardous area classification for gasoline pumps and, with due consideration to the safety level,

revise the requirements in accordance with internationally-accepted standards, as necessary, to facilitate the introduction of self-service gasoline pumps equipped with electronic point-of-sale devices (such as credit card processing systems);

- (2) Accept Underwriters Laboratories (UL) certification to the extent that it conforms with IEC standards for electrical components used in the manufacture of gasoline pumps after UL is approved as a foreign inspection institute designated by the Minister of Labour; and
- (3) Initiate a study of the duplications between the certification process required to obtain designated manufacturer status and those required to obtain ISO 9001/9002 certification, with a view toward their possible omission, and will conclude this study by no later than the end of CY 2000.

6. **Energy Sector Restructuring:** The U.S.-Japan Working Group on Energy Deregulation was established in May 1998. The Government of Japan and the Government of the United States exchanged views on Japanese Government plans for energy sector deregulation, as well as the ongoing restructuring of this sector in the United States, and both sides shared the view that the goal of deregulation in the energy sector is the introduction of a more competitive market, which would lead to a more efficient, rational, and less expensive supply of energy. The two sides also shared the view that in implementing deregulation in this sector, the two governments should be mindful of its potential effects on public welfare, energy security, and the environment. Both sides deepened their understanding of the current status and future prospects for deregulation in the energy sector.

## F. DISTRIBUTION

### 1. Customs/Import Processing

- (1) The Government of Japan established a prior classification information system using e-mail in 1998.
- (2) The Government of Japan will institute Electronic Data Interchange (EDI) filing for import-export permits and approvals under the provisions of the Foreign Exchange and Foreign Trade Law by the end of FY 1999.
- (3) **Measures to be taken in FY 1999:** The Government of Japan will:
  - (a) Introduce a system for maritime container cargo, which allows importers to obtain permission to import upon confirmation of transferring cargo into the customs area;

- (b) Complete the study on NACCS (Nippon Automated Cargo Clearance System) to promote the link with the import-export system being developed under the provisions of the Foreign Exchange and Foreign Trade Law, and the computer system of the Ministry of Transportation for handling procedures at the port; and
  - (c) Support World Customs Organization adoption of the revised Kyoto Convention, which promotes the use of harmonized, simplified and streamlined cargo processing systems to facilitate international trade.
- (4) The Government of Japan has re-confirmed the decision by the Cabinet in March 1995 concerning “The Deregulation Action Program” that bonded warehouses in the vicinity of Narita Airport can be permitted if there is no problem from the viewpoint of control by Customs and promptness of Customs Clearance.

## **2. Retailing and Services**

- (1) Fundamental Changes of Policy Concerning Large-Scale Retail Stores: The Government of Japan introduced the Daiten-Ricchi-Ho (Law Concerning the Measures by Large-Scale Retail Stores for Preservation of Living Environment) from the viewpoint of abolishing supply/demand adjustment concerning the opening and operating of large-scale retail stores and preserving the living environment surrounding such stores. A legislative measure was taken to implement the new law from June 1, 2000 and abolish the current Large-Scale Retail Store Law on the same day;
- (2) In implementing the Daiten-Ricchi-Ho (the Law), the Government of Japan, in order to facilitate the consistent, transparent and predictable application of the Law, will take the following measures:
- (a) The Ministry of International Trade and Industry (MITI) will establish a detailed Guideline, which will be finalized around the first half of 1999, as a national standard, for consideration by entities intending to establish a large-scale retail store (store openers) with regard to the preservation of the living environment, such as traffic and noise. The Guideline will also provide local governments with detailed criteria, as a national standard, to use in presenting opinions and making recommendations;
  - (b) In developing cabinet orders, if any, ministerial ordinances, the Guideline, and other measures to implement the new Law, MITI will follow the "Public Comment Procedure" which was adopted on March 23, 1999;



- (c) The Law, cabinet orders, ministerial ordinances and other measures will prescribe all of the requirements and the procedures that local governments and store openers will be required to follow with regard to the establishment or expansion under the Law of large-scale retail stores.
  - (d) MITI will:
    - (i) Closely monitor local governments' implementation of the Law to ensure that the purpose of the new Law is not impeded;
    - (ii) Establish a contact point in MITI to receive and facilitate resolution of complaints from any interested party regarding the application of the Law; and
    - (iii) Take appropriate measures, as necessary, based on the Local Autonomy Law, including giving technical advice and recommendations to local governments, to facilitate resolution of complaints from any interested party regarding the application of the Law.
- (3) The 1998 revision of the City Planning Law abolished the classifications of Special Land Use Districts. In designating Special Land Use Districts, local governments will provide for public review of the proposed designation, hold public hearings on the proposed designation, allow interested parties to comment on the proposed designation, and require the City Planning Council (*Toshi Keikaku Chihou Shingikai*) to conduct an objective and transparent review of the comments. Based on the public comments, local governments will issue transparent and neutral decisions.
- (4) Liquor: With regard to liquor retail licenses, the restriction on the number of licenses issued per a definite population has been steadily phased out beginning September 1998, to be abolished as of September 1, 2003. The restriction on proximity to existing premises will be abolished on September 1, 2000.

### **3. Transportation**

- (1) Trucking Business
  - (a) The fare and fee system of trucking business will be studied in the direction of achieving a more liberalized system and the study will be completed by around the end of FY 1999.

- (b) The operation zones of trucking businesses were enlarged to cover entire regional economic blocs.
- (2) Warehousing: The entry system of warehouse business in the direction of minimizing governmental regulations, as well as fee notification system in the direction of achieving a more liberalized system, will be studied. Each study will be concluded as early as possible.
- (3) Freight Forwarding Business: With regard to the notification system for fees and charges in the freight forwarding business for motor vehicles (i.e., trucks, vans and other freight-carrying motor vehicles), based on the system for trucking business, for which the submission of cost account statements are not required, was extended to within the range of 20 percent of the difference of standard fees in FY 1998.
- (4) Port Transportation Business: Based upon the final report submitted by the Administrative Reform Committee in December 1997, which recommended replacement of the port transportation business licensing system with a permit system, replacement of the current fee approval system with a notification system, and the examination and implementation of various measures for ensuring stability of port transportation, the Port Transport Subcommittee of the Maritime Transport Committee of the Transportation Policy Council conducted a study beginning in May 1998 and issued its interim report in December 1998. Public comment procedures are being applied to the interim report.

## **G. ANTIMONOPOLY ACT AND COMPETITION POLICY**

### **1. Competition Policy Advocacy**

- (1) The Japan Fair Trade Commission (JFTC) conducted a survey on the Antimonopoly Act (AMA) Compliance Programs of the top 2,372 firms in Japan and publicized its survey report in June 1998.
- (2) The JFTC conducted three surveys and actively addressed violations of the AMA with regard to *min-min kisei* or “private regulations.”
- (3) The Government of Japan will provide for the following:
  - (a) From April 1999, in order to support the voluntary efforts by firms to develop a methodology to comply with the AMA, the JFTC will begin assisting the Japan Fair Trade Institute (JFTI) to formulate a model AMA Compliance Program, which will revise and improve the current “Guide for AMA Compliance Programs.”

- (b) By the end of FY 1999, to facilitate consultations from firms or trade associations regarding whether their proposed business plans comply with the AMA, the JFTC, in cooperation with local chambers of commerce, will establish an Antimonopoly Act Consultation Network.
- (c) The JFTC will use appropriate fora, including initiating public hearings, to actively address important deregulation and competition policy issues in Japan.
- (d) To promote competition, the JFTC, from the viewpoint of the AMA and competition policy, has actively coordinated with other government organs regarding proposed economic legislation and regulatory measures and, when appropriate, the JFTC has expressed its views at the opportunities of Cabinet meetings. The JFTC has also actively expressed its opinions at meetings of advisory councils and study groups, which are established and hosted by government agencies. The JFTC is firmly determined to continue to actively address these types of issues and will remain in principle committed to this approach after the central government reform in 2001.
- (e) To promote competition, the JFTC will actively review business entry regulations and “supply/demand adjustment regulations” and, when appropriate, will publicly propose removing such regulations to relevant government ministries and agencies.
- (f) Based on its recognition that intervention into the market by government organs through the use of administrative guidance may create competition-distorting effects, ministries and government agencies concerned will closely bear in mind the purpose of “The Antimonopoly Act Guidelines regarding Administrative Guidance” and will enter into necessary consultations in advance with the JFTC to ensure that government regulations are not replaced by competition-restricting administrative guidance.
- (g) To promote competition, the JFTC will actively engage in competition policy advocacy by reviewing competition-restricting regulations, which exist on the central government and prefectural government levels, and, when appropriate, by proposing abolishment or revision of such regulations.
- (h) To promote competition, when eliminating and deregulating government regulations, it is indispensable that *min-min kisei* or “private regulations,” which restrain competition, do not become substitutes for former

government regulations. From this viewpoint, the JFTC will actively eliminate market entry restrictions by trade associations or other entities when they violate the AMA. The JFTC will also conduct surveys on economic and business conditions, and when finding private trade practices that restrain competition, will actively rectify them and, when administrative guidance is found to support such private trade practices, will actively request government ministries and agencies concerned to withdraw and refrain from such guidance.

- (i) To promote the understanding and transparency of the AMA enforcement, the JFTC will continue to make its thinking on provisions of the AMA easy to understand by issuing and revising guidelines and by publicizing major examples of consultations with firms and trade associations. In February 1999, the JFTC announced revised draft guidelines on patent and know-how licensing agreements and is soliciting comments from interested parties before the finalized guidelines are issued.

## 2. **Private Remedies**

- (1) The Ministry of International Trade and Industry's (MITI) study group on private party injunctions issued its final report in June 1998. The report concluded that it is necessary to permit private parties to bring injunctions against unfair business practices.
- (2) The JFTC's study group on private remedies issued its interim report on private party injunctions in December 1998. The report concluded that private party injunctions against AMA violations may be "appropriate," subject to further review on specific points, within the framework of the AMA.
- (3) The Government of Japan:
  - (a) Will, on the basis of the reports issued respectively by study groups of the JFTC and MITI, further actively promote consideration of private remedies with a view towards improving Japan's private remedy system against unfair business practices, including AMA violations; and
  - (b) Will aim to reach a conclusion by the end of FY 1999 after obtaining the final report from the JFTC's study group, which is to be submitted to the JFTC by the end of December 1999 at the latest.

## 3. **Anticartel Enforcement**

- (1) The Government of Japan:

- (a) Took measures to secure full compliance with Section V.6(l), “Confirmation in Tendering Documents,” of the “1994 Action Plan on Reform of the Bidding and Contracting Procedures for Public Works.” The twelve ministries and agencies and sixteen quasi-government agencies, which are members of the Central Liaison Council for Implementation of Public Works Contract Systems (*Chuo Kokyo Koji Keiyaku Seido Unyo Renraku Kyogikai*), as a result, fully comply with the action plan by requiring participants in bidding to confirm in tendering documents that they recognize they may not engage in practices inconsistent with the AMA, and that they are indeed not involved in such practices.
  - (b) To increase transparency in the bidding process, adopted the policy of disclosing the scheduled price (*yotei kakaku*) for public works projects after the results of bids are released and most of the procuring agencies comply with the policy.
- (2) The Government of the United States notes that in February 1999, the JFTC filed a criminal accusation with the Public Prosecutor General against three manufacturers of ductile iron pipe for colluding to fix the market share for each firm. In March 1999, the JFTC filed an additional criminal accusation against ten of the sales staff from the manufacturers.
- (3) The Government of the United States notes that in FY 1998, the JFTC took formal legal actions in 27 cases of AMA violations, 19 of which were unreasonable restraints of trade such as cartel arrangements and bid-rigging.
- (4) In furtherance of the OECD Recommendation (March 25, 1998) concerning *Effective Action Against Hard Core Cartels*, the Government of Japan will provide for the following:
- (a) The JFTC will continue actively to enforce the AMA against violations such as cartel arrangements and bid-rigging. Under the JFTC’s 1990 policy to file criminal accusations for egregious and serious violations of the AMA by actively seeking criminal penalties, the JFTC will continue to direct its investigatory efforts against such violations and will actively file criminal accusations.
  - (b) The JFTC will make further efforts to strengthen its investigatory powers system with the understanding of the relevant parties. The JFTC will make further efforts to strengthen its investigatory powers by: improving training programs for staff of the Investigation Bureau; increasing the technical expertise for staff of the Investigation Bureau; and reviewing, with a view towards improving, rules related to investigation procedures.

- (c) The Government of the United States understands that the *Nyusatsu Kokoroe* (the Bidding Instructions) sets conditions of bidding for public works only from the standpoints of procurement entities, and that failing to comply with the *Nyusatsu Kokoroe* does not automatically constitute an illegal act, but failing to comply with the *Nyusatsu Kokoroe* could result in nullification of the bid.

The Ministry of Construction will add the following two paragraphs to the Article 4-3 of the *Nyusatsu Kokoroe*, provided that the Government of the United States confirms the above understanding.

“2. The bidders must determine the prices in the bid independently without any consultation with any other bidders or potential bidders for the purpose of restricting competition relating to: (a) prices; or (b) the intention to submit a bid.

3. The bidder must not knowingly disclose the prices in the bid to any other bidders or potential bidders before contract award.”

#### 4. **Distribution**

(1) The JFTC:

- (a) Publicized in June 1998 the result of its follow-up survey concerning the implementation of measures by relevant photographic color film and paper industry firms in response to JFTC suggestions in its July 1997 survey; and
- (b) In Summer 1998, initiated a follow-up survey of the flat glass industry to assess the current state of competition and how firms have addressed the JFTC's suggestions.

(2) The JFTC will:

- (a) Closely monitor and actively enforce the AMA in accordance with the “Guidelines concerning Distribution Systems and Business Practices” in the retail distribution sector, among others, in light of recent changes; and
- (b) Complete and publish the results of its flat glass survey as soon as possible.

#### 5. **Antimonopoly Law Exemptions**

- (1) The Cabinet on February 16, 1999 submitted a bill to the 145<sup>th</sup> Diet Session to abolish the Depression and Rationalization Cartels and other AMA exemptions.

- (2) The JFTC will further consider reviewing the AMA exemption systems from the viewpoint that continuous review is required to limit the exemption systems as much as possible to the necessary minimum, taking into consideration the changes in future circumstances.

## 6. Merger Policy

- (1) The Government of the United States notes that in December 1998, the JFTC announced the finalized guidelines on stockholdings and mergers.
- (2) The Government of Japan will, through the JFTC:
  - (a) Publicize on a timely basis major examples of prior consultation with firms to improve the transparency of the prior consultation process in merger reviews; and
  - (b) Endeavor to devote more staff and resources to merger matters.

## 7. JFTC's Budget, Resources and Organization

- (1) The Government of Japan proposed to the Diet a FY 1998 budget that increased the JFTC's budget by 1.1% and its staff by 10 persons; and the FY 1998 budget was approved by the Diet in April 1998.
- (2) The Government of Japan submitted a FY 1999 budget to the Diet that proposed to increase the JFTC's staff by 9 persons, to be assigned mainly to the Investigation Bureau, and its budget by 2.8%; and the FY 1999 budget was approved by the Diet in March 1999.
- (3) The Government of Japan will take all necessary measures to maintain the JFTC's independence, especially regarding personnel matters and policymaking matters, when the JFTC becomes part of the Ministry of General Affairs in 2001.

## H. LEGAL SERVICES

1. An amendment to the Special Measures Law Concerning the Handling of Legal Business by Foreign Lawyers was enacted in August 1998, which expanded the objectives of joint enterprises between a *gaikokuho-jimu-bengoshi* (foreign legal consultant) and a *bengoshi* and relaxed experience requirements and certain other restrictions on *gaikokuho-jimu-bengoshi*.

2. The Government of Japan will request the Japan Federation of Bar Associations (Nichibenren) to remove the prohibition against advertising by lawyers, other than reasonable minimum rules necessary to ensure that advertising is neither false nor misleading, within FY 1999.

## **I. MOTORCYCLES**

As for the motorcycle speed limit on expressways, the Government of Japan is considering what regulation is most suitable in Japan from the view of traffic safety, taking into consideration several factors, such as analyses of actual traffic accidents. The Government of Japan will finish this consideration by around the end of FY 1999, and within FY 2000, take necessary measures based upon the conclusion of the consideration.

## **J. TRANSPARENCY AND OTHER GOVERNMENT PRACTICES**

### **1. Public Comment Procedure**

- (1) The Management and Coordination Agency (MCA) drafted and announced “Public Comment Procedure for Formulating, Amending or Repealing a Regulation” to invite comments and information from the public and entrepreneurs from November 5, 1998 to December 10, 1998 on the proposed Procedure. After studying various comments and information submitted, the Cabinet adopted the Procedure by issuing a Cabinet Decision on March 23, 1999. The Procedure was implemented at the beginning of the new fiscal year (April 1, 1999).
- (2) In implementing the new Procedure, the Government of Japan will make maximum efforts so that central government entities will apply the Procedure as broadly as possible.
- (3) In order to ensure that the Procedure is properly implemented, the MCA will follow-up its implementation and publish its findings.
- (4) Pending the adoption and implementation of government-wide Public Comment Procedure, several government entities, including advisory councils, have used, on their own initiative, public comment procedures before issuing significant regulations or reports.

### **2. Application Process**

- (1) **Streamlining and Expediting the Application Process:** The MCA conducted a review with an aim of reducing the standard processing period for the issuance of licenses, permits and approvals and announced the results in September 1998. The standard processing period for 1380 application processes, out of 3,602



application processes, were shortened, of which the standard processing periods for 580 items were reduced by half.

- (2) **Examination Standards:** The Government of Japan is reviewing examination standards for the issuance of licenses, permits and approvals with the aim of clarifying, specifying, and quantifying the examination standards while minimizing discretionary factors, in accordance with the Three-Year Deregulation Program (decided by the Cabinet on March 31, 1998).
3. **Implementation of the Administrative Procedure Law:** The MCA has conducted surveys on implementation of the Administrative Procedure Law since the Law became effective in October 1994 and has gathered information on the implementation of the Law, such as the institution of examination standards. In accordance with the Three-Year Deregulation Program, the Government of Japan continues to promote compliance with the Law, and to enhance transparency and clarity in the administrative measures and administrative guidance pertaining to application processes. To enhance the understanding of the requirements of the Administrative Procedure Law, the Government of Japan has prepared and distributed a pamphlet, entitled “Administrative Procedure Law, Common Rules on Examination of Applications for Permissions, Notifications, and Administrative Guidance.”
4. **Information Disclosure Law:** The Government of Japan submitted “The Access to Government Information Bill” (tentative translation) and other relevant bills to the Diet in March 1998. The information disclosure bill under deliberation in the Diet includes a provision that the government will take legal and other necessary measures regarding information disclosure by public corporations (*tokushu hojin*).
5. **Overall Greatest Value Methodology in Local Government Procurement:** The Government of Japan adopted an ordinance amending a part of the implementing ordinance of the Local Autonomy Law in February 1999, so as to introduce the Overall Greatest Value Methodology (OGVM) as one method of determining the successful bidder in local government procurement; it was effective immediately.

## **DEREGULATION AND OTHER MEASURES BY THE GOVERNMENT OF THE UNITED STATES UNDER THE ENHANCED INITIATIVE**

### **A. ISSUES UNDER THE DEREGULATION AND COMPETITION POLICY WORKING GROUP**

1. **Government Procurement Procedures: Buy American Laws:** The Government of the United States will continue dialogue with the Government of Japan relating to the "Buy American Provisions," which affect market access of foreign products and services to the U.S. market.
2. **Exon-Florio Clause:** The Government of the United States has provided the Government of Japan with a clarification of the national security provision in the Exon-Florio clause.
3. **Metric System:** The National Institute of Standards and Technology of the Department of Commerce is considering seeking an amendment to the Fair Packaging and Labeling Act that would permit the option of metric-only labeling on products that fall under the Act. The National Conference on Weights and Measures intends to amend the Uniform Packaging and Labeling Regulations to permit manufacturers the option of metric-only labeling on products that are only regulated by the states.
4. **Re-export Controls:** The United States applies both permissive re-export treatment under relevant Commerce Department regulations, as well as a *de minimus* rule to Japan. The Department of Commerce will continue to discuss with Japan on issues of concern in the areas of re-export controls. The United States is prepared to take additional steps to inform Japanese exporters of controlled U.S.-origin goods, technology and software about the requirements of current U.S. re-export control regulations and will make this information available on a U.S. Government website and other media, such as a pamphlet. In this regard, the United States will develop guidance for Japanese exporters on their obligations under U.S. Export Administration Regulations.
5. **Customs Issues:** The U.S. International Trade Commission (ITC) is currently conducting a study of the Harmonized Tariff Schedule of the U.S. (HTSUS) for the purpose of simplifying the U.S. tariff structure. The ITC's simplification study will include the tariff structure for watches and clocks, and is scheduled to be completed by the summer of 2000.
6. **Labeling Requirement of Origin for Clocks and Watches:** The Government of the United States has clarified the grounds for the labeling requirement of origin for straps of watches by providing the Government of Japan with the relevant administrative regulations.

7. **NAFTA Rule of Origin for Textile and Apparel Products:** The Government of the United States conveyed to other NAFTA members the request of the Government of Japan to review NAFTA origin rule for textile and apparel products, and will continue a discussion with the Government of Japan on the issue.
  8. **American Automobile Labeling Act of 1992:** The National Highway Traffic Safety Administration (NHTSA) is conducting an evaluation of the impact of the motor vehicle labeling program established under the American Automobile Labeling Act, and has surveyed manufacturers, including Japanese manufacturers, as part of this evaluation. NHTSA will solicit public comments from all interested parties on this evaluation by the summer of 2000.
  9. **Corporate Average Fuel Economy (CAFE) Standards:** The Government of the United States will continue a discussion with the Government of Japan on issues of concern to Japan relating to CAFE standards.
  10. **Anti-Dumping Measures:** Both the United States and Japan acknowledge the importance of the work of the WTO Committee on Anti-Dumping Practices and the appropriate use of its mechanisms.
  11. **Visa/Immigration Issues:** Responsible executive branch agencies are considering ways to ameliorate the difficulties faced by children of foreign business professionals who wish to complete their studies at U.S. public high schools.
  12. **Antitrust Law Exemptions:** In October 1998, the Government of the United States narrowed the judicially created antitrust exemption for baseball with the passage of the Curt Flood Act. At the Department of Justice, the review of antitrust exemptions is an ongoing matter.
  13. **Legal Services:** The states in which substantial international business transactions are conducted have foreign legal consultant rules. The United States supports the adoption by other states of such rules.
- B. HOUSING:** The United States supports the activities of the International Code Council to develop and promulgate performance-based standards in the United States, which is slated for completion in the year 2000. In that effort, it would support the participation of Japan and other interested parties in these and other activities in the building standards area in the United States.

**C. TELECOMMUNICATIONS**

1. **International Charging Arrangements for Internet Services:** The Government of the United States will actively participate in the APEC effort to study the traffic flow and cost structure of the Internet.
2. **FCC Order Concerning International Benchmarks:** The Government of the United States will actively cooperate in, and make contributions to, the multilateral discussions in the ITU and other fora to address the issue of above-cost accounting rates.
3. **Application Procedures:** In March 1999, the Government of the United States revised application procedures for international communications services such as the shortening of the period for streamlined certification. Furthermore, in February 1999, the Government of the United States introduced a pilot program for electronic filing of applications as a means of simplifying the application procedure.
4. **Access to Intelsat:** The Federal Communications Commission (FCC) has issued a proposed rulemaking to consider the appropriate conditions for permitting direct access to INTELSAT from the United States.
5. **State-level Regulations:** The National Telecommunications and Information Administration (NTIA) has initiated a process to provide Japan with opportunities to address concerns regarding state-level regulatory matters.

#### **D. MEDICAL DEVICES AND PHARMACEUTICALS**

1. The Food and Drug Administration (FDA) has been working with the Ministry of Health and Welfare (MHW) through exchanges and the like to facilitate a mutual confidence building process to promote the mutual recognition of Good Manufacturing Practices. This cooperative process will be actively pursued. In addition, FDA and MHW are working actively in international harmonization fora, such as the International Conference on Harmonization.
2. The FDA is now meeting the 90-day review for 510(k) devices and has eliminated the backlog. Noting there is still substantial delay in the review period for some devices which are allocated for CBER, FDA will continue to work toward a more timely review of these applications.

#### **E. FINANCIAL SERVICES**

1. **Abbreviated Exams for Foreign Securities Dealers:** The Securities and Exchange Commission approved the abbreviated exam proposals for the New York Stock Exchange, the National Association of Securities Dealers, Inc. and the American Stock Exchange on January 11, 1996, April 12, 1996 and September 15, 1997, respectively.

2. **Examination of Foreign Banks:** The Federal Reserve, together with other supervisors participating in the FBO program (the Enhanced Framework for Supervising the U.S. operations of Foreign Banking Organizations), continue to improve the efficiency and coordination of the examination process. For example, on August 25, 1998, the Federal Reserve, along with the Office of the Comptroller of the Currency (OCC) and the Federal Deposit Insurance Corporation (FDIC), issued an interim rule and requested public comment on a proposal to expand the examination frequency cycle of for certain U.S. branches and agencies of foreign banks (e.g., assets < \$250 million; well managed and well capitalized) from every 12 month to every 18 months.
3. **Citizenship Requirements:** Section 72 of the National Bank Act requires that directors of National banks must be citizens of the United States. In the case of an OCC-licensed national bank or affiliate of a foreign bank, the Comptroller of the Currency may at his discretion waive the citizenship requirement in the case of not more than a minority of the total number of directors. The OCC will continue to implement this requirement in such a way as to cause minimal disruption. Many states which have citizenship requirements also (depending on the individual state law) waive such requirements.
4. **Financial Modernization (HR 10):** The principles of National treatment and equality of competitive opportunity were embodied in the financial modernization legislation under discussion in the last Congress; and the Government of the United States will work to ensure that any future legislation also embodies these principles.
5. **Supervision of Foreign Bank Branches:** The Conference of State Bank Supervisors, working with foreign banks and supervisors, developed two agreements to improve coordination and consistency of supervision for foreign banking organizations operating in more than one state. The agreements are designed to provide for a seamless and flexible supervisory process and minimize regulatory burden and cost. Agreements have been signed by all states with foreign banking operations, all foreign banks with multi-state banking operations and federal banking regulators.
6. **Regulation of Securities Firms:** The National Securities Markets Improvement Act has minimized overlap between federal and state securities registration requirements, and prohibits states from limiting or imposing conditions on the sale of most securities.
7. **Interstate Banking:** Effective June 1, 1997, bank holding companies and foreign banks with subsidiaries in more than one State may merge or consolidate these banking subsidiaries into a single bank with interstate branches (except in states that specifically prohibit such interstate branching networks.)
8. **Expansion of the List of Activities Contained in Regulation Y:** In 1997 the Federal Reserve Board expanded the list of activities (contained in Regulation Y) that bank holding companies and foreign banking organizations are permitted to engage in to

include: riskless principal, private placement, proprietary trading and other activities that had been previously approved only in individual Board orders. The Board also adopted streamlined application or notification procedures for bank holding companies or foreign banks to engage in regulation Y activities or to acquire a firm engaged in such activities.

9. **Amendment of Regulation K:** In December 1997, the Federal Reserve Bank proposed amending Regulation K which governs the foreign operations of U.S. banks and U. S. operations of foreign banks. Among other proposals, the revisions would change how Qualifying Foreign Banks Organization status is calculated for purposes of determining eligibility for certain exemptions from nonbanking restrictions.