FOURTH JOINT STATUS REPORT ON THE U.S.-JAPAN ENHANCED INITIATIVE ON DEREGULATION AND COMPETITION POLICY
June 30, 2001

In the fourth year of the U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy (Enhanced Initiative), the Governments of the United States and Japan reaffirmed their determination to promote further deregulation, apply effective competition policy and devote substantial resources to implementation of the Enhanced Initiative.

Throughout the fourth year, the two Governments convened regular meetings of the High-Level Officials Group and of the Expert-Level Groups, (telecommunications, housing, medical devices and pharmaceuticals, financial services, energy, and structural issues, including information technology, competition policy, commercial code reform, legal reform, distribution, and issues related to transparency and other government practices). Consistent with the principles of two-way dialogue and the aim of achieving tangible progress, both sides exchanged views on a wide variety of deregulation items. As part of that effort, the Governments of the United States and Japan provided submissions to each other in October 2000.

The Government of Japan has taken a series of deregulatory measures, the latest and the most significant being the adoption on March 30, 2001 of the Three-Year Program for Promoting Regulatory Reform. The salient deregulatory and other measures by both Governments that relate to the work under the Enhanced Initiative are set out in this Joint Status Report. The two Governments welcome the progress that has been achieved under the Enhanced Initiative over the past four years. 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 regulatory reforms. The two Governments, upon the request of either government, will meet at a mutually convenient time to address the measures contained in this report. The two Governments also affirm their determination to build upon the progress achieved under the Enhanced Initiative through the Regulatory Reform and Competition Policy Initiative, which is a key component of the newly established U.S.-Japan Economic Partnership for Growth.

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

I. TELECOMMUNICATIONS

A. Promotion of Competition

1. In order to promote further competition in the Telecommunications Business Field, the Government of Japan submitted to the Diet amendments to the Telecommunications Business Law, NTT Law, and related laws. These amendments include the introduction of new asymmetric regulations to eliminate anti-competitive behavior of major telecommunications carriers which are assumed to have market power and the establishment of the Telecommunications Business Dispute-settlement Commission. The amendments passed the Diet on June 15, 2001.

2. The new asymmetric regulations include:

   a. Anti-competitive safeguards are applied to the following two categories of telecommunications carriers:

      (1) A Type I telecommunications carrier with Category I-designated telecommunications facilities (regional fixed networks).

      (2) A Type I telecommunications carrier with Category II-designated telecommunications facilities (mobile networks) and designated by the Minister of Public Management, Home Affairs, Posts and Telecommunications on account of the carrier's market share, the change in its share, and other aspects.

   b. For carriers categorized as either (1) or (2) above, the regulations clarify three sets of prohibited behaviors:

      (1) The abuse or provision of proprietary information obtained from competitors through interconnection for purposes other than interconnection;

      (2) Unduly favorable or unfavorable treatment of specific telecommunications carriers; and

(3) Undue compulsion or intervention towards manufacturers, suppliers of telecommunications equipment or content providers.

c. To take action against such behavior, effective measures (order to suspend/change behavior) enabling quick correction of violation thereof are introduced under the revised law.

d. The revised law provides for a legal "firewall" between a telecommunications carrier with designated regional fixed networks and its parent, subsidiary, or other affiliated carriers designated by the Minister of Public Management, Home Affairs, Posts and Telecommunications. These "firewall" restrictions include:

(1) Prohibition of concurrency of board members;

(2) Ensuring equal treatment with respect to the use of buildings/facilities and the provision of information necessary for interconnection; and

(3) Ensuring equal treatment upon being entrusted with various services.

e. Effective measures (non-penal fines or order of suspension/change of behavior) for rapidly correcting violation thereof and the requirement for telecommunications carriers with designated regional fixed networks to annually report compliance thereof are established under the revised law.

f. Formulating and changing user tariffs (except user rates, currently subject to notification), interconnection tariffs and facilities-sharing agreements of telecommunications carriers with designated regional fixed networks remain in place under the existing approval system, but formulating and changing tariffs, interconnection agreements and facilities-sharing agreements of other carriers no longer require approval but only notification, and items to be notified will be stipulated in relevant ordinances.

g. Interconnection tariffs of telecommunications carriers with designated mobile networks are required to be established, notified, and publicly disclosed. When those tariffs prove not to reflect appropriate costs under efficient management, revisions may be required.

3. After promulgation of the above-mentioned amendments and in accordance with the related articles, the Ministry of Public Management, Home Affairs, Posts and

Telecommunications (MPHPT) will amend its ordinances in consultation with the Telecommunications Council. The Council will invite public comments as necessary.

4. In CY 2001, MPHPT will draft guidelines in consultation with the Telecommunications Council to identify competitive conditions for NTT East and/or West to be granted authorization to expand their scope of business under Article 2.5 of the revised NTT Law.

5. Under the new, competitively neutral universal service funding mechanism, eligible telecommunications carriers may receive universal service support as part of financial compensation for the cost of universal service (subscriber telephone services, public telephone services, and emergency call services) provision, which will be determined by a long-run incremental cost (LRIC)-based costing methodology.

6. All Type I and Special Type II carriers will be able to offer wholesale services more flexibly by notification of a contract or a tariff. Items to be notified will be stipulated in relevant ordinances.

B. **Interconnection**

1. MPHPT approved in February 2001 the LRIC-based interconnection rates from FY2000 to FY2002 applied for by NTT East and West for functions related to the provision of telephone and ISDN services. This resulted in, for example, a 7.1 (GC interconnection, 180 sec.) – 23.1 (ZC interconnection, 180 sec.) percent decrease for FY 2001 interconnection rates for PSTN compared to FY 2000 rates.

2. MPHPT approved in February 2001 NTT East's and West's applications to phase out the interconnection rate for the I-interface subscriber module (ISM) switching function over three years from FY2000 to FY2002, which will eliminate the differential between ISDN interconnection and PSTN interconnection.

3. Based on the recommendations in the report of the Study Group on the LRIC Model, held from March 1997 to September 1999, and the Telecommunications Council's Report "Policy on Calculation of Interconnection Charges" of February 2000, MPHPT re-established the Study Group in September 2000 and has been conducting a study on the revision of the LRIC model. The items to be studied include depreciation rates, choice and price of inputs, the costing of local loops, and the scope of non-traffic-sensitive costs. This study is expected to be concluded in around February 2002.

4. Regarding flat-rate based interconnection charges, which could help stimulate Internet usage through flat-rate based network usage charges, MPHPT invited public comments

in January and February 2001 on such issues as specific calculation methods. Currently, a study is being conducted by the Telecommunications Council, which issued a draft report “Policy on Interconnection Rules in the IT Era” in May 2001 to invite public comments. On receipt of the Council’s final report, MPHPT will take appropriate measures.

5. MPHPT approved in March 2001 the reduction of interconnection rates charged by each NTT DoCoMo company, from 18.1 yen/minute to 15.2 yen/minute, for interconnection at a point of interface within its own service area with other carriers. The reduced rates were implemented retroactively from April 1, 2000.

C. **Rights of Way**

1. The Government of Japan researched the voluntary measures for improvement taken by Type I telecommunications carriers, electric utility companies, and railroad and subway operators and published reports in October 2000 and March 2001.

2. The Government of Japan continued to receive complaints and opinions with regard to laying of cables during FY 2000 and reviewed the circumstances of "Rights of Way" and access to incumbent facilities for the laying of cables. The results of the review were published on April 3, 2001.

3. The Government of Japan specified measures for facilitating laying of cables in "The e-Japan Priority Policy Program" established on March 29, 2001, under Article 35 of the Basic Law on the Formation of an Advanced Information and Telecommunications Network Society. These measures included steps to provide public space within FY 2001 for 29,000 km of optical fiber and to publicize this via the Internet. The Government also listed a series of related measures that will be implemented over three years from FY 2001 to FY 2003 for the purpose of further opening facilities such as poles and conduits, and smooth laying of cables in public space such as roads in "The Three-Year Regulatory Reform Program" adopted by the Cabinet on March 30, 2001.

4. To make it easier for Type 1 telecommunications carriers to lay cables and to promote the construction of fiber-optic networks indispensable to establishing the ultrahigh-speed Internet, MPHPT issued "Guidelines for Use of Utility Poles, Ducts, Conduits, etc." prescribing fair, non-discriminatory and transparent rules for the use of utility poles, ducts, conduits, etc. owned by telecommunications carriers, electric power companies and railroad companies. Based on the Guidelines, reasons for rejecting access will be specified. The Guidelines have been in effect since April 1, 2001.

5. The Government of Japan submitted to the Diet amendments to the Telecommunications Business Law, NTT Law, and related laws to reinforce a dispute settlement procedure which would apply to disputes over rights of way by 1) establishing coordination procedures with the agencies involved in the use of public land such as roads and 2) stipulating a requirement for the Minister of Public Management, Home Affairs, Posts and Telecommunications to consult with and receive a recommendation from the Telecommunications Business Dispute-settlement Commission when conducting an arbitration. The amendments passed the Diet on June 15, 2001.

D. **Unbundling**

1. MPHPT amended its ordinances in September 2000 to ensure that the "Articles of Agreement concerning Interconnection" of NTT East and West include interconnection rates and technical conditions regarding interconnection with unbundled metal subscriber lines and with ISM loop-back function. MPHPT approved necessary revisions of the Articles before the end of FY 2000. This will permit competing carriers providing high-speed access services for Internet usage to reach subscribers directly without building their own subscriber lines.

2. Following the Telecommunications Council's Report "Revision of Interconnection Rules" of December 2000, in order to promote broadband services and fair competition, MPHPT amended its ordinances in April 2001 to require NTT East and West to stipulate in their "Articles of Agreement concerning Interconnection" 1) interconnection rates for subscriber line and inter-office dark fibers, 2) technical conditions regarding interconnection with dark fibers, and 3) procedures for competitors to obtain from NTT East and West the information necessary for interconnection with fiber-optic facilities, including such details as materials and availability. Having received the relevant applications for the revision of the Articles, MPHPT consulted the Telecommunications Council in May 2001. After receiving a report from the Council, MPHPT will take appropriate measures.

3. In April 2001, in order to secure conditions for fair competition regarding data transmission services, MPHPT 1) issued a public notification designating facilities such as transmission facilities that offer data transmission services and routers that assign carriers and 2) amended its ordinances to require NTT East and West to calculate interconnection rates for their regional Internet Protocol (IP) networks by unbundling them and to stipulate the rates in their "Articles of Agreement concerning Interconnection." Having received the relevant applications for the revision of the Articles regarding interconnection rates for unbundled functions of regional IP networks, MPHPT consulted the Telecommunications Council in May 2001. This will

permit carriers to access NTT regional companies' IP networks on a non-discriminatory basis. After receiving a report from the Council, MPHPT will take appropriate measures.

4. MPHPT amended its ordinances in April 2001 to require NTT East and West to stipulate in their "Articles of Agreement concerning Interconnection" procedures to allow other carriers to use inside wiring owned by NTT East and West. Having received the relevant applications for revision of the Articles, MPHPT consulted the Telecommunications Council in May 2001. After receiving a report from the Council, MPHPT will take appropriate measures.

E. **Co-location:** To improve the opportunities for co-location, MPHPT amended its ordinances in September 2000 (effective from October 2000) to require NTT East and West to stipulate in their "Articles of Agreement concerning Interconnection:"

1. Procedures to allow interconnecting carriers to undertake, on an expeditious basis, construction and maintenance regarding co-located facilities;

2. Procedures to provide interconnecting carriers with 24-hour access to their equipment co-located in the buildings of NTT East or West;

3. A standard period for NTT East and West to reply to co-location requests and undertake the necessary construction for co-location;

4. Procedures to disclose information on available space for co-location; and

5. Procedures to allow interconnecting carriers to enter the buildings of NTT East and West to see the availability of space for co-location if they receive a reply that such space is not available.

MPHPT approved the relevant revisions of the Articles in November 2000.

F. **Resale**

1. With regard to leased lines, MPHPT amended its ordinances in November 2000 to require NTT East and West to stipulate discount rates for carriers (Carriers' Rates) in their "Articles of Agreement concerning Interconnection." MPHPT approved the rates in January 2001, which cover ATM and other digital leased line services. The discount rate is based on the differentials between costs for carriers and end-users. The discount rates for digital services range from 8.6 percent to 24.3 percent.

2. The Telecommunications Council's Report "Revision of Interconnection Rules" of December 2000 recommends that detailed studies should be continued to implement discount PSTN rates for carriers. The Report mentions that those studies should pay careful attention to the differences between leased lines and PSTN. These studies are being conducted by the Telecommunications Council.

G. **Spectrum Management:** The Government of Japan amended the Radio Law to introduce a procedure for comparative selection of applicants for radio station licenses and to draw up and publish "The Frequency Allocation Plan" stipulating such items as the frequencies assignable for each purpose of radio stations, and the amended Radio Law came into effect in November 2000. Public Comments are invited in compiling or amending the criteria for comparative selections and "The Frequency Allocation Plan," which are subsequently made public.

H. **Others**

1. MPHPT amended its ordinance in November 2000 to enable a Type I telecommunications carrier to use telecommunications circuit facilities, procured from another telecommunications carrier on a user-tariff basis, as part of its own network, and to operate the whole network for the Type I business.

2. MPHPT amended its ordinances in April 1999 concerning the provision of dialing parity and the amended ordinances came into effect in December 2000. MPHPT approved in March 2001 applications for the revision of the "Articles of Agreement concerning Interconnection" of NTT East and West regarding interconnection rates and construction fees that enable dialing parity. Carriers started offering dialing parity on May 1, 2001.

3. MPHPT amended its ordinances in August 1999 concerning the provision of number portability and the amended ordinances came into effect in December 2000. MPHPT approved in March 2001 applications for the revision of the "Articles of Agreement concerning Interconnection" of NTT East and West regarding interconnection rates and construction fees that enable number portability.

II. INFORMATION TECHNOLOGY

A. Liability of Internet Service Providers (ISPs)

1. The Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT) established the Study Group for Appropriate Information Distribution over the Internet in May 2000, to study necessary measures to address the distribution of illegal information via the Internet. The Study Group studied

the liability of ISPs. The Study Group compiled a report in December 2000 based on its study, and the public comment procedure was conducted on the report for about a month period for comment submission.

2. Taking into account the recommendations made in the report and the comments it has received, MPHPT is currently drafting a bill for the purpose of clearly stipulating the liability of ISPs for any type of illegal information put on the Internet, including defamation, invasion of privacy and copyright infringement, in a horizontal manner, while appropriately considering the balance between the interests of the person who claims that his/her rights have been violated and the senders of the information, so that the ISPs will take prompt and appropriate counter measures. The Government of Japan will continue a dialogue on this issue with the Government of the United States.

B. **Intellectual Property**

1. Temporary Copies: The Government of Japan will continue a dialogue on this issue with the Government of the United States.

2. WIPO Performances and Phonograms Treaty (WPPT): The Government of Japan supports the entry into force of the WPPT. In order to ensure expeditious entry into force, the Government of Japan will submit the WPPT to the Diet as soon as possible.

C. **Privacy:** Regarding personal information protection, the Experts Committee for Legislation on Personal Information Protection issued the "Outline of Fundamental Legislation for Personal Information Protection" in October 2000. The Outline clearly states that an appropriate balance between the "protection" and "use" of personal information must be properly maintained, and it supports the establishment of a basic and common framework for the protection of personal information in the private sector, allowing for self-regulatory dispute resolution mechanisms. The Government of Japan submitted legislation to the Diet in March 2001 that is consistent with this basic policy.

D. **E-Commerce Legal Framework**

1. The Government of Japan implemented a general review of the existing regulations which are recognized as a hindrance to the development of e-commerce, including the statutory and administrative regulations prescribing the requirement to submit paper documents, the requirements of face-to-face based declaration of intent, and the requirements to establish branch offices in Japan. The regulations concerning paper-based requirements were reviewed by the Cabinet Secretariat. The other regulations were jointly reviewed by the Cabinet Secretariat and the Regulatory Reform Committee. The result of the general review was published in September 2000.

2. Taking into account the result of the general review, a law which comprehensively amends 50 existing laws including laws prescribing the obligation of issuance of paper and procedures with paper between private entities, passed the extraordinary session of the Diet in 2000. The law came into effect in April 2001.

3. The Government of Japan will continuously consider amending existing laws and regulations which hinder the development of e-commerce, including the requirements for face-to-face transactions, for locating offices in Japan, and for preserving paper documents.

E. **Electronic Government Procurement**

1. Goods and Services (Excluding Public Works):

a. The Government of Japan has established a uniform system for examining the qualifications of companies interested in participating in competitive bidding, and for preparing a list of qualified bidders for each procurement. Under this system, an application for qualification for any government ministry/agency is considered valid for all ministries and agencies. The system has been used in the regular examination process since January 2001.

b. The Government of Japan will start operating within 2001 a consolidated database of government procurement information that brings together the information of each ministry/agency that is provided in their respective websites. This information will be posted on one website- http://www.chotatujoho.go.jp/va/com/TopPage.html.

2. Public Works: The Government of Japan will start electronic bidding utilizing the Internet for some projects commissioned by government ministries and agencies from October 2001. In principle, the electronic bidding will be introduced for all projects directly commissioned by the central government ministries and agencies by end of FY 2004. The Ministry of Land, Infrastructure and Transport will establish by the end of FY2004 the system of CALS/EC (Continuous Acquisition and Lifecycle Support/Electronic Commerce).

F. **Promotion of Trade in Digital Products:** The Government of the United States and the Government of Japan will cooperate in multilaterally promoting policies which ensure liberalized treatment for trade in digital products and expanded use of e-commerce in all economies.

G. **Security**

1. The Government of Japan and the Government of the United States share the view that the Organization for Economic Cooperation and Development (OECD) Guidelines for the Security of Information Systems should be an important basis for national approaches to information security.

2. In support of the OECD's review of these Guidelines, the Government of Japan will host a workshop organized by the OECD focusing on information security in an era of global networks in September 2001 in Tokyo.

3. The Governments of Japan and the United States will work with other member countries of the OECD to contribute to the Guidelines review and ensure a transparent review process.

4. The Government of Japan established the "Special Action Plan on Countermeasures to Cyber-Terrorism of Critical Infrastructure" in December 2000 to protect the critical infrastructures from cyber-terrorism attacks. The Government of Japan is also working to establish cooperation and communication systems between the Government of Japan and the private sector. The target date to establish the systems is the end of CY2001.

5. The "IT Security Expert Meeting," comprised of knowledgeable representatives from the private sector, and the "IT Security Promotion Committee," comprised of representatives from all Japanese government ministries and agencies, were established in January 2001 under the IT Strategy Headquarters, to strengthen IT security through cooperation between the Government of Japan and the private sector.

III. MEDICAL DEVICES AND PHARMACEUTICALS

A. Recognition of Innovation

1. In 2000, to enhance transparency of the drug pricing system, MHLW took measures such as the codification of the drug pricing rule as well as the establishment of the Drug Pricing Organization. MHLW will discuss the remaining issues for drug pricing reform listed below with the aim of finalizing measures by April 1, 2002. These reforms will result in appropriate valuations of pharmaceuticals that fully recognize the value of innovative products in order to encourage faster introduction and broader availability of innovative products which bring more effective and more cost-effective treatments to patients. During this process, MHLW will seriously consider the proposals and views of industry, including U.S. industry, through active dialogue at various stages of the reform process. MHLW will consider benefits and shortcomings of the current system as well as alternatives, focusing on:

a. The adjustment zone;

b. The handling of original products and generics;

c. Premiums; and

d. Others (e.g.(1) rules related to re-pricing following expansion of market size, and (2) price adjustment in comparison with prices in other countries).

2. In May 2001, the Drug Classification Committee concluded its work and proposed its draft drug classification for comparator selection to MHLW. MHLW has made this draft public, and is providing opportunities to concerned parties, including U.S. industry, to express their comments on the draft for two months, ending July 23, 2001. This work for drug classification has been and will be carried out based on pharmaceutical and clinical principles, whose result will appropriately recognize the value of innovative pharmaceuticals.

3. In October 2000, to improve the process and enhance the transparency of the reimbursement pricing procedures for medical devices, MHLW subdivided categories for granting reimbursement (e.g., A1 to C2) and revised the definitions and time-clocks for granting reimbursement for each category. This system will result in appropriate valuations of medical devices that fully recognize the value of innovation. To encourage faster introduction and broader availability of innovative products which bring more effective and cost-effective treatments to patients, MHLW will continue to discuss pricing rules regarding the new by-function categories (C1, C2) and will consider the timing for granting reimbursement. Regarding the consideration of these matters, Chuikyo has listed various matters for discussion. The U.S. side is requesting written rules , criteria and procedures for application, review and establishment of C1 and C2 provisional pricing as well as final pricing that reflect clinical and economic considerations, while MHLW will provide meaningful opportunities for interested parties, including U.S. industry, to present their proposals and views, which will be given serious consideration.

4. The process of creating by-function prices for the medical devices which are now reimbursed based on actual purchase prices by medical care facilities will continue to allow affected companies meaningful opportunities to discuss matters of their concern, such as perceived disproportionate burdens, directly with MHLW.

B. **Approval Process**

1. MHLW has further increased the scope of medical devices that do not require clinical trials for approval to include wound dressings.

2. On March 28, 2001, MHLW issued an official publication which includes flowcharts that clearly outline the steps for the approval of "improved" and "new" medical devices. This system provides for direct communication between applicants and reviewers, including opportunities to meet with external experts. It also establishes a roadmap mechanism in the early stage of the review process whereby applicants can present the salient points of applications to reviewers.

3. MHLW will maintain an active dialogue with related parties, including U.S. industry, in order to ensure that the new category of "improved devices" does not narrow the definition of "me-too devices," and to increase the speed of medical device approvals. MHLW will develop and publish a decision tree to clarify the three categories ("me-too," "improved," and "new") for medical device approvals.

4. On May 24, 2000, MHLW issued a notification that establishes opportunities for prior consultations on medical device applications within the context of the medical device approval process, and clarified the contact points for such consultations. MHLW will strive to ensure the consistency between advice on medical device applications provided in prior consultations by reviewers and treatment after submission.

5. MHLW offers opportunities, as appropriate, for medical device applicants to discuss their applications with senior MHLW officials.

6. MHLW, METI, and interested parties, including U.S. industry, continue consultations regarding the treatment of thermometers and blood pressure gauges under the Pharmaceutical Affairs Law (PAL) and the Measurement Law (ML). MHLW and METI will study various ways of lessening potential data burdens on applicants for thermometers and blood pressure gauges which are subject to approval (*shonin*) under PAL as well as type test (*katashiki-shonin*) and individual unit verification (*kentei*) under ML.

7. MHLW continues dialogues about the comments on biocompatibility testing requirements from related parties, including U.S. industry, and will present a revised draft on the requirement for further comments in the near further, with the objective of minimizing the data burdens on applicants.

8. Over the last three years, MHLW has implemented many important improvements to the New Drug Application (NDA) pharmaceutical approval process which have resulted in a reduction of review times. MHLW has achieved steady progress toward

its goal of reducing the standard processing period for NDAs to12 months for NDAs submitted in and after April 2000. MHLW will continue to work to speed the process and continue the dialogue with related parties, including U.S. industry, in order to make this overall progress more steady. The U.S. Government will continue to urge U.S. companies to compile and submit high-quality NDAs.

9. In November 2000, MHLW issued an official publication which includes a flowchart that clearly outlines the steps for the approval of pharmaceuticals. This system provides for direct communication between applicants and reviewers, including external experts. It also establishes a road map mechanism whereby applicants can present the salient points of applications to reviewers in the early stage of the review process as well as an interview review meeting six months, in principle, after submission to discuss key issues, which are communicated to applicants two weeks before the meeting. Applicants can bring their own experts to this meeting, and afterwards applicants will be given an indication of "approval" or "non-approval."

10. Japan will implement a new early post-marketing phase vigilance system for newly approved pharmaceuticals on October 1, 2001 which will treat domestically and internationally developed products identically.

C. **Acceptance of Foreign Clinical Data**

1. MHLW and reviewing bodies have increased the acceptance of foreign clinical data and will continue to accept foreign clinical data as primary evidence of clinical safety and efficacy.

2. On a case-by-case basis through consultations with the Organization for Pharmaceutical Safety and Research (OPSR), considering such factors as dose regime, clinical endpoints, etc., the possibility can be considered of not requiring an additional bridging study for an additional similar indication when data to establish extrapolation exists to support the initial indication of a molecule.

3. MHLW will work constructively within the International Council on Harmonization (ICH) to identify the problems with the ICH E-5 guideline including, the interpretation of racial groups as well as if and under what conditions additional data would be necessary to establish extrapolation scientifically in order to develop supplemental guidance to make the guideline more easily implementable.

4. MHLW continues to provide opportunities to exchange views on bridging issues with related parties, including U.S. industry, presents important points to consider and

relevant guidance based on the experiences of clinical trial consultations at open fora such as seminars as well as encourages the use of consultations at OPSR.

D. **Transparency**

1. On October 1, 2000, the Drug Pricing Organization (DPO) and the Special Organization for Insurance-covered Medical Materials were established. These entities provide appeals processes for pharmaceutical and medical device pricing decisions. MHLW, which retains overall responsibility for outcomes, has ensured and will ensure that these entities provide sufficient time and access for applicants to present views and discuss relevant matters. These entities will conduct appeals processes according to the written pricing rules and impartially, according serious consideration to applicants.

2. In order to enhance the transparency in revising pharmaceutical and medical device pricing systems, MHLW, upon request from foreign pharmaceutical and medical device manufacturers, will continue to provide them 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 MHLW officials at all levels. MHLW will provide sufficient time for meaningful discussions and will seriously consider the proposals and views of industry, including U.S. industry, through active dialogue at various stages of the reform process.

E. **Nutritional Supplements**

1. Based on the recommendations of the Office of the Trade and Investment Ombudsman (OTO), on April 1, 2001, MHLW implemented a new system governing the treatment of "so-called nutritional supplements," which allows such products to make nutritional and health benefit claims where there are scientific data and information to support such claims. Liberalization of future products will be assessed within the context of this new system and the OTO recommendations. MHLW will ensure that the data requirements of this regulatory system are reasonable and appropriate, and limited to requirements necessary to ensure safety and efficacy. MHLW will continue to use foreign data and information to the maximum extent possible for product approval, and will assess nutritional and health benefit claims in the same manner.

2. Regarding additives (as defined in Japan, e.g., vitamins, minerals and excipients) which are used in food with health claims in forms different from ordinary food such as capsule and tablet form, MHLW made it possible in the newly established guidelines (Procedures for Designation and for Revision of Standard for Use) to omit a one-year toxicity study if the additives have been used as ingredients for pharmaceutical products.

F. **Health Care Services**

1. On March 1, 2001, amendments to the Medical Services Law were implemented to allow further advertising by hospitals, including clinical trials being undertaken, health consulting services, foreign and sign language ability of staff, accreditation by the Japan Council for Quality Health Care, and medical examination services.

2. The Government of Japan will continuously endeavor to review regulation of its health care sector with an aim to improving efficiency and quality of services provided.

IV. ENERGY

A. **Energy Sector Liberalization:** The Government of Japan and the Government of the United States exchanged views on Japan's progress and plans for further energy sector regulatory reform, as well as the ongoing restructuring of this sector in the United States. The two sides discussed measures aimed at development of a more competitive energy market, which would lead to Japan's goal of a more efficient, rational and less expensive supply of energy for Japan. These measures take into consideration potential effects on public welfare, energy security, and the environment. The two sides also shared the view that these measures should be taken prudently, recognizing that careful consideration of lessons learned from other countries, including the risks for security as well as benefit through regulatory reform, is necessary. Based on these shared views, the Government of Japan is taking and will continue to take regulatory reform measures in the energy sector.

B. **Regulatory Authorities**

1. The newly formed Electricity Market Division within the Ministry of Economy, Trade and Industry (METI) became responsible for regulation of Japan's electricity market as of January 2001. The Government of Japan will continue to work to ensure this new entity has effective, independent authority over electricity regulation, including:

   a. Ensuring the Electricity Market Division works with the Japan Fair Trade Commission (JFTC) to promote fair and open access to electricity transmission networks (In FY 2000, METI worked jointly with JFTC to review and address 20 requests for advice pertaining to application of the Antimonopoly Act.);

   b. Securing sufficient resources and staff with relevant expertise in the Electricity Market Division, which was allocated a larger staff than its predecessor organization; and

c. Maintaining the independence of the Electricity Market Division through relevant provisions.

2. The newly formed Gas Market Division within METI became responsible for regulation of Japan's gas market as of January 2001. The Government of Japan will continue to work to ensure this new entity has effective, independent authority over gas regulation, including:

a. Ensuring that the Gas Market Division works with JFTC to promote fair and open access to gas transportation networks;

b. Securing sufficient resources and staff with relevant expertise in the Gas Market Division; and

c. Maintaining the independence of the Gas Market Division through relevant provisions.

C. **Competition Policy Safeguards**

1. JFTC will enforce the AMA and relevant guidelines against exclusionary activities that impede access to the Japanese electricity or gas markets in a manner that substantially restrains competition or that has the effect of preserving or extending market power. Electricity and gas markets will be actively monitored to ensure compliance with the Guidelines on Fair Electricity Transactions and the Guidelines on Fair Gas Transactions. METI and JFTC will, as appropriate, expand and clarify both Guidelines as further experience is gained as to the types of conduct that may give rise to competitive problems.

2. In April 2001, JFTC established in its Investigation Bureau the IT and Public Interest Business Task Force, which will focus on suspected AMA violations in, among other areas, the electricity and gas sectors. This Task Force is composed of a Chief Investigator and several investigators, who will cooperate with the staff of sections outside the Investigation Bureau within JFTC and experts outside JFTC if necessary.

3. Under the AMA, JFTC strictly reviews mergers and acquisitions in any market, including the electricity and gas markets, that might cause anticompetitive concerns.

D. **Public Comment Procedure:** In the development of cabinet orders, ministerial ordinances, notifications and other measures related to energy, METI will, to the extent possible, allow a 30-day comment period, and where appropriate and possible, a longer time period.

E. **Electricity:** The Government of Japan is taking and will continue to take regulatory reform measures to ensure fair and effective competition in its electricity market.

1. METI recognizes that non-discriminatory access to the transmission grid is necessary to achieve a competitive electricity market and recognizes that it is necessary to distinguish transmission activities from generation and other activities in order to achieve and monitor such non-discriminatory access. During FY 2001, METI will:

   a. Ensure accounts for transmission services by utilities for FY 2000 be made public;

   b. Conduct an audit of utility accounts, including accounts for transmission services, implemented in FY 2000, to assess whether the wheeling tariff is just and appropriate, and make the assessment public; and

   c. Continue to monitor the transparency and neutrality of wheeling services in order to achieve non-discriminatory access.

2. METI recognizes that fair and transparent treatment of wheeling service requests from new entrants, including those cases which need capacity expansion, is required for a competitive electricity market. METI will therefore:

   a. Continue to require utilities to study and respond to such requests in a fair and reasonably speedy manner, by providing information, including the interconnection specifications for new transmission lines to their networks; and

   b. Monitor the need for new transmission line construction as a more competitive electricity market develops.

3. Recognizing that new entry into the Japanese electricity market will facilitate the Government of Japan's goals of lower electricity prices and increased efficiency and innovation, METI will take measures to promote new entry, which include:

   a. Conducting a study, as appropriate, of existing regulatory requirements for siting of new generating units and transmission lines to ensure timely construction while preserving the public policy objectives sought by these regulations;

   b. Consulting actively with parties interested in entering the market (METI provided advice in 44 cases involving new entrants and made this information publicly accessible on the Internet.); and

c. Ensuring fair treatment of all consumers and competitors in the marketplace through the recently established formal, comprehensive dispute-resolution mechanism, which mediates disputes between various market participants, including new entrants.

4. The Government of Japan recognizes that the privatization of the Electric Power Development Company (EPDC) should be carried out in a manner consistent with the AMA and Japan's policies on regulatory reform of its electricity market, and the privatization should not be implemented in a manner that hinders competition. In addition, the Government of Japan will ensure that the acquisition of any EPDC facilities is subject to review under the AMA.

5. METI is taking a number of measures to improve the quality and transparency of information available to participants in the electricity market. These measures include:

a. Implementing a third-party audit in CY 2001 in order to prevent cross-subsidizing from regulated activities to liberalized activities and publicly disclosing the results where losses are found to have occurred in liberalized activities; and

b. Continuing to conduct semi-annual surveys of electricity price data in each utility service area to enable industry and consumers to track the progress of regulatory reform in reducing electricity prices over time. Furthermore, METI will analyze the survey results to evaluate the impact of current regulatory reform in achieving competition.

6. METI will conduct and make publicly available an evaluation of the progress of electricity market regulatory reform to date, including the status of new entry into this market, by 2003.

F. **Gas:** The Government of Japan is taking and will continue to take regulatory reform measures to ensure fair and effective competition in its gas market.

1. METI recognizes that realizing a fair and transparent gas market, together with a well developed gas transportation system, can contribute to effective competition in Japan's electricity market.

2. Recognizing the role of transportation infrastructure development in energy market growth, METI will publish a list of major regulatory requirements for siting of new pipelines and LNG facilities.

3. In order to help ensure non-discriminatory access to gas transmission services for competing gas suppliers, METI established rules in January 2001 requiring large-scale general gas utilities to establish fair and transparent terms and conditions for open access to their pipeline networks.

4. METI has begun to study Japan's gas market in a comprehensive and transparent manner. METI, for example:

   a. Established in January 2001 a Gas Market Development Basic Issues Study Group to examine a wide range of possible issues that could increase the gas market's transparency and efficiency (The group includes many respected experts from academia and industry, and its deliberations are open to the public.); and

   b. Has conducted studies on the status of liberalization in other nations.

5. METI will implement and enforce administrative rules on gas rate and tariff accounting methodology, transmission rate calculations at existing utility-owned gas pipelines, and other terms and conditions that were established and publicly announced by METI in January 2001.

6. METI will address complaints pertaining to the newly deregulated gas market in a fair and impartial manner based on the Guidelines on the Settlement of Disputes.

7. METI is taking and will take measures to improve the quality and transparency of information available to participants in the gas market. These include:

   a. Conducting a study by METI's City Gas Tariff Working Group in FY 2000 on rate calculation mechanisms and transparency, the results of which were published in November 2000; and

   b. Promptly implementing guidelines on information disclosure for gas rates and tariffs, pipeline transmission rates and tariffs, and other terms and conditions which were established and publicly announced by METI in January 2001.

8. METI will conduct and make publicly available an evaluation of the progress of gas market regulatory reform to date, including the status of new entry into this market, by 2003.

V. FINANCIAL SERVICES

A. **Specific Measures:** The Japanese financial system reform program (the so-called Japanese" Big Bang"), which was started at the initiative of 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." All of its measures have been implemented according to schedule.

Regarding issues stated in the request on deregulation submitted by the US government to the Japanese government last October 12, the introduction of an electronic delivery system for prospectuses has already been implemented, as mentioned in the following statement. In addition, measures such as the introduction of a defined contribution pension plan and modification of systems using the Internet regarding application and registration procedures by financial institutions are to be implemented, aiming to further activate our financial market. Furthermore, in cases where self-regulatory organizations should define policies regarding their members, standards of screening, and the application of disciplinary measures related to authority granted by the law, it is appropriate that steps similar to the public comment procedures of the Japanese government be taken. For example, the Japan Securities Dealers Association and stock exchanges have already introduced public comment procedures, and efforts have been made to improve transparency in the financial sector.

1. The following measures, in addition to the measures described in the former Joint Status Reports, have already been implemented:

    a. Removal of the ban on entry of subsidiaries of banks into insurance business (Oct. 1, 2000).

    b. Removal of the ban on over-the-counter sales of insurance by banks. (Sales of certain products have been allowed since April 1, 2001.)

    c. Regulatory improvements expanding the scope of eligible assets for securitization by special purpose companies and making the system more convenient to use. (The relevant laws and regulations took effect on Nov. 30, 2000.)

    d. Clarification of the standards for granting exemptions from firewall regulations. (Ministerial Ordinance and Guidelines were revised on June 30, 2000.) An application procedure was finalized in early 2001, and the first approvals under this process have already been issued.

    e. Introduction of the electronic delivery system for prospectuses (Apri1 2001). The Securities Report and semi-annual reports may now be filed electronically (June 1, 2001). The electronic filing of the Securities Registration Statement

will be allowed, with the date of enforcement proposed as a date to be prescribed, by Government Ordinance by June 1, 2002.

f. Modification of the provisions concerning management of the *Nempuku* successor fund (Government Pension Investment Fund) through the introduction of a new trust scheme (*tokutei houkatsu shintaku*) as an alternative to the limited partnership scheme when using investment advisory companies for management of assets of the Government Pension Investment Fund. This new trust scheme allows the GPIF to directly employ investment advisory companies, and the GPIF is also allowed to transfer securities in kind when shifting business from one assets manager, who is a trust bank or an investment advisory company, to another (Apri1, 2001).

g. Introduction of exchange-traded funds (ETFs) tracking stock price indexes, and allow their establishment through contributions in kind (June 6, 2001).

h. The Financial Services Agency (FSA) has been working actively on the effective implementation of the current system of responding to inquiries concerning the interpretation of laws and regulations, described in the Joint Status Report last year. Based on the cabinet decision of March 27, 2001 regarding the so-called Japanese "no-action letter" system, the FSA will introduce the new system, as early as possible within this fiscal year.

2. In addition, to continuously enhance financial market reform, the following measures are to be implemented from now:

a. Permitting the entry of a bank into trust business directly. (The bill to partially amend the Banking Law, etc was submitted to the Diet, with the date of enforcement proposed for Oct. 1, 2001.)

b. Amendment of provisions pertaining to entries into banking businesses by non-financial entities. (The bill to partially amend the Banking Law, etc was submitted to the Diet, with the date of enforcement proposed as a date to be prescribed by Government Ordinance within six months from the date of promulgation.)

c. Dematerialization of Commercial Paper (CP). "The bill on transfer (book entry system) of short-term corporate debentures" has passed the Diet, and is scheduled to enter into force from April 1, 2002. The Japanese government will consider dematerialization of additional investment products.

d. The bill to introduce a defined contribution pension scheme has passed the Diet, and is scheduled to enter into force from October 1, 2001.

e. Introduction of a system allowing the use of the Internet in application and registration procedures by financial institutions. (Implementation scheduled to be completed by fiscal 2003.)

B. *Kampo* (Postal Insurance)

1. The Government of Japan reaffirms section IV.B.2. of the Third Joint Status Report on the U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy, issued in July 2000.

2. Regarding the future of the Postal Life Insurance System (*Kampo)*, the Basic Law on the Administrative Reform of the Central Government of 1998 provided for MPHPT and the Postal Services Agency in January 2001, and later MPHPT and the new postal public corporation (*yusei kosha*), to take over the management of the Postal Life Insurance system, and to implement the system, reflecting the objective set out in the Postal Life Insurance Law, as well as the basic ideas in the Administrative Reform Program adopted by the Cabinet on December 25, 1996. MPHPT is currently considering the framework of the Postal Life Insurance Law which is to be applied in the new public corporation system.

3. Considering the provision in the Postal Life Insurance Law, which stipulates that the purpose of Postal Life Insurance is to promote the welfare of the public, and the interest of private parties, including foreign insurance providers, in the modification of the *Kampo* system, MPHPT recognizes the importance of informing the general public of the formulation of the amendments of the provisions concerning *Kampo* products in the Postal Life Insurance Law which the transfer to the new public corporation would affect, before the bill is submitted to the Diet.

4. MPHPT will provide an opportunity for private interested parties, including foreign insurance providers, upon request, to comment on, and exchange views with MPHPT regarding the formulation referred to above.

VI. HOUSING

A. Secondary Housing Market

1. Access to Information: The Ministry of Land, Infrastructure and Transport (MLIT) will continue to provide assistance to the Real Estate Transaction Modernization Center to

revise the manual for evaluating existing homes, both detached and collective, so that maintenance and renovation quality of homes are reflected in a new, standardized model for resale price evaluation.

2. Promoting Benefits of Maintenance and Renovation: MLIT has taken various opportunities to heighten public awareness of how maintenance and renovation can be used to enhance the quality of existing homes. These opportunities include the annual one-month nationwide housing event sponsored by MLIT in cooperation with municipalities. MLIT will hold this event in October 2001. Enhancing durability can improve the quality of existing homes as well as yield environmental benefits. MLIT continues to consider various measures to build and expand the secondary housing market.

3. Financing: The Government of Japan has already reduced the registration tax on existing homes from 5 percent to 0.3 percent -- the same as that for new homes (in the case of transfer registration). Recognizing the importance of this measure to the sales of existing homes, the Government of Japan has extended the measure to March 31, 2003. Following the amendment of the Government Housing Loan Corporation (GHLC) Law, from FY 2000, the maximum repayment term for resale condominiums meeting certain quality criteria has been extended from 30 to 35 years, which is the same as that for newly built homes. Similarly, the maximum repayment term for resale detached homes meeting certain quality criteria has been extended from 20 to 25 years.

B. **Public Comment Procedures:** In the development of cabinet orders, ministerial ordinances, notifications and other measures related to the Building Standard Law and the Housing Quality Assurance Act. MLIT will, to the extent possible, allow a 30-day comment period, and where appropriate and possible, a longer time period.

C. **Building Regulations and Standards**

1. The Government of the United States is working with the Ministry of Agriculture, Forestries and Fisheries (MAFF) to develop the necessary documentation in order for MAFF to confirm whether the grading system for wood products in the United States is equivalent to the Japan Agricultural Standard (JAS) system. The Government of the United States intends to provide the documents in the very near future. On receipt of the documents that are required for conducting the equivalency examination, MAFF will make a good faith effort to make a determination as regards equivalency as soon as possible.

2. Recognizing that building standards should be transparent, allow the introduction of new products and systems, and be based upon objective performance criteria, the then-

Ministry of Construction amended the Building Standards Law (BSL) to introduce performance-based codes in 1998, beginning June 1, 2000. To facilitate implementation, the Government of Japan will publish and disseminate its test methodology for evaluating fire resistance.

3. In November 2000, the then Ministry of Construction (MOC) notified designated administration agencies and designated confirmation and inspection bodies that the correction factors for plywood are to be applied to Oriented Strand Board (OSB), thereby confirming their equivalency.

4. The Government of the United States and the Government of Japan will continue to have technical discussions in fora such as the Building Experts Committee, the JAS Technical Committee and the Wood Products Subcommittee on such issues as performance-based codes, implementation of test methodologies and procedures in evaluating fire resistance.

VII. COMPETITION POLICY AND ANTIMONOPOLY LAW

A. JFTC Independence

1. After the government reorganization in 2001, JFTC's independence is being preserved as before.

2. "Structural Reform of the Japanese Economy: Basic Policies for Macroeconomic Management" ("Basic Policies"), which was adopted in the form of the Cabinet Decision on June 26, 2001, states that the Government of Japan will review the status of the JFTC to make it more appropriate from the viewpoint of its independence and neutrality from the regulatory authorities in the new system of governmental ministries and agencies.

B. Strengthening AMA Enforcement

1. The Government of Japan will examine policy measures, including the introduction of legislation, to enable the JFTC to effectively expose violations of the Antimonopoly Act (AMA).

2. In February 2001, JFTC established the AMA Study Group, which includes two working groups. The "Procedural Regulation Working Group" is examining a variety of issues related to improving enforcement of the AMA. Those issues include:

   a. Expanding the scope of surcharge orders;

b. Expanding the scope of appropriate measures against acts that have already ceased to exist;

c. Extending the period to issue recommendations or initiate hearing procedures;

d. Improving criminal accusation procedures;

e. Improving overseas service of process; and

f. Providing lenient treatment of companies and individuals that cooperate in JFTC investigations.

3. The Study Group will submit its report to JFTC for improving AMA enforcement in the Fall of 2001. In light of that report and other factors, JFTC will take appropriate measures, including the preparation of necessary legislation.

4. JFTC reaffirms that it will apply AMA §3 to such conduct as cartels and group boycotts which cause a substantial restraint of competition. Furthermore, where such conduct curtails the volume of supply in Japan, and thereby affects the price of goods or services in Japan, JFTC will issue surcharge orders on participants of such conduct.

5. JFTC will enforce all the provisions of the AMA in a manner that promotes price competition in all sectors of the economy.

C. **Eliminating *Dango* (Bid Rigging)**

1. The Government of Japan will examine the introduction of legal measures, including new systems to address the procuring agencies and officials who are involved in *dango*.

2. Where *dango* activities are found to have been based on administrative guidance, JFTC, in accordance with its Guidelines on Administrative Guidance, will work with the concerned agency to eliminate such administrative guidance and to ensure that the agency does not issue administrative guidance that conflicts with the AMA.

3. In order to promote proper tendering and contracting of public works, including elimination of *dango*, by Central Government agencies, quasi-governmental agencies and local governments, the Act for Promoting Proper Tendering and Contracting for Public Works was enacted. The Act, which came into effect on April 1, 2001:

a. Obliges all commissioning entities to report facts that raise a suspicion of *dango* to JFTC;

b. Requires the Central Government, through a Cabinet Decision, to issue the Guiding Principle on measures for promoting proper tendering and contracting for public works;

c. Stipulates that the Central Government, quasi-governmental agencies and local governments make efforts to provide education and training, as well as other necessary measures, to ensure that tenders and contracts for public works are properly executed; and

d. Authorizes MLIT, MPHPT and MOF to request commissioning entities to submit a report on measures taken in accordance with the Guiding Principle and to take measures that are particularly necessary to promote proper tendering and contracting for public works.

4. In accordance with the Act, the Cabinet issued a Decision to adopt the Guiding Principle. The Guiding Principle obliges the commissioning entities to make efforts to:

a. Make and publish a manual, which will include procedures to follow to report facts raising a suspicion of *dango* to JFTC;

b. Make clear the firm attitude against illegal activities, including *dango*, and to implement "suspension of designation" strictly in order to prevent a recurrence of the illegal activities;

c. Claim compensation for overcharges as a result of *dango* when the recognition of the amount of the loss is available; and

d. Handle strictly illegal activities of government officials, including the organizing or assisting of *dango*, and to execute the education and training of government officials in order to prevent such activity.

5. JFTC and the National Police Agency (NPA) will continue to examine what kind of consultation or cooperation, including the cooperation in their respective investigations into *dango* activities, is practicable.

D. Promoting Competition in Industries Undergoing Deregulation

1. JFTC will play an active role in promoting competition in industries undergoing deregulation.

a. In January 2001, JFTC published the "Report on Deregulation and Competition Policy in Public Utility Sectors" prepared by the Study Group on Government Regulations and Competition Policy.

b. JFTC will, as necessary for the execution of its proper duties, continue actively to survey, study and make policy proposals from the viewpoint of competition policy regarding public utility sectors, including electric power and gas services, where deregulation is under way.

c. JFTC is preparing AMA Guidelines for business practices in the telecommunications industry. It will publish draft guidelines this year, and will solicit and consider public comments before issuing the final guidelines. An English language version of the draft guidelines will be published at the same time as they are published in Japanese.

d. The JFTC's Study Group on Government Regulation and Competition Policy will issue its final report, which is expected to include advice on how to promote competition in the convergent sectors of telecommunications and broadcasting, by the end of 2001.

2. JFTC and MPHPT will endeavor to take action to cooperate from the viewpoint of promoting competition in telecommunications sectors, including the establishment of joint guidelines, which would incorporate the guidelines mentioned in paragraph 1c above.

3. JFTC has established the Information Technologies and Public Utilities Task Force in its Investigation Bureau to investigate and take enforcement action against violations of the AMA in industries undergoing deregulation, such as the telecommunications, electricity and gas sectors. The Task Force can be contacted through its website – www.jftc.go.jp/task.htm – and complaints of AMA violations may be submitted directly to the Task Force.

E. Increasing Resources of JFTC

1. In FY 2001, the number of JFTC's staff has increased by eleven officials, which will be mainly assigned to the Investigation Bureau in order to strengthen its investigation activities and capabilities.

2. "Structural Reform of the Japanese Economy: Basic Policies for Macroeconomic Management" ("Basic Policies"), which was adopted in the form of the Cabinet Decision on June 26, 2001, states that the Government of Japan will strengthen the

structure and the function of JFTC, so that the Government of Japan can strongly implement competition policy.

F. **Surveys to Promote Competition:** JFTC will survey one or more sectors in FY 2001, which may include highly oligopolistic industries.

VIII. TRANSPARENCY AND OTHER GOVERNMENT PRACTICES

A. Public Comment Procedure

1. Since the beginning of FY 1999, the Government of Japan has implemented the "Public Comment Procedure for Formulating, Amending or Repealing a Regulation" (Public Comment Procedure). Under this Procedure, the administrative organization will make public the comments and the information submitted, and its views on them. Even when the comments and information are published in a summarized form, the comments and information will be made available for review by the public in their original form in a reading room in the organization or in other forms, for a certain period of time.

2. The MPHPT is conducting a follow-up examination of the implementation of the Public Comment Procedure in FY 2000, as the Ministry did for FY 1999. In cases where the public comment period was less than 28 days, the reasons for setting that period in individual cases have been added to the current follow-up examination. The MPHPT will publish its findings in the near future.

3. The following organizations have decided to introduce the Public Comment Procedure: (1) Japan Securities Dealers Association (JSDA); (2) Japan Craft Inspection Organization (JCI); and (3) The Investment Trusts Association. JSDA and JCI have already implemented the Procedure.

B. "No Action Letter" System

1. The Cabinet on March 27, 2001 adopted Guidelines for the Introduction of Prior Clearance Procedures for Application of Laws and Ordinances by Administrative Organs (*Gyousei kikan ni yoru hourei tekiyou jizen kakunin tetsuzuki no dounyuu ni tsuite*), a so-called "No Action Letter" system. Under the new system, businesses may submit inquiries to ministries and agencies related to the interpretation and application of laws and ordinances to specific factual situations. The ministries and agencies will respond in writing to inquiries within 30 days, in principle, and will make their responses public.

2. Before the end of FY 2001, each ministry and agency will adopt detailed Rules related to its implementation of the new "No Action Letter" system.

C. **Policy Evaluation System**

1. In January 2001, the Government of Japan introduced a government-wide policy evaluation (*seisaku hyoka*) system to improve the transparency of the government, to strengthen the government's accountability to the public, and to improve the quality of public administration. Under this system, all ministries and agencies have established policy evaluation sections and are evaluating policies from such viewpoints as need, efficiency and effectiveness. In addition, the MPHPT, as the ministry responsible for the management of the policy evaluation system, evaluates the policies of the ministries and agencies to ensure the comprehensiveness and strict objectivity of their policy evaluations, and makes necessary recommendations to the ministries and agencies. The policy evaluations are made public.

2. The Government of Japan established in January 2001 the Commission on Policy Evaluation and Evaluation of Independent Administrative Institutions (*Seisaku Hyoka Dokuritsu Gyosei Hojin Hyoka Iinkai*), comprised of independent experts, to ensure that the MPHPT's policy evaluations are conducted in a fair and neutral manner.

3. The Government of Japan submitted legislation for a Government Policy Evaluation Act (GPEA), to the ordinary session of the Diet in 2001, to enhance the effectiveness of the policy evaluation system and the accountability of ministries and agencies. The GPEA was enacted in June 2001, and the Government will implement the GPEA, beginning in April 2002.

4. The Government will make continuous efforts to enhance and strengthen the policy evaluation system, and will review the system as necessary.

D. **Examination of New Regulations:** The secretariats and other competent coordination sections of the individual ministries and agencies will examine regulations that they propose to introduce under the basic principle that regulations should be restricted to the minimum level necessary. To this end, when introducing new regulations, the individual ministries and agencies will conduct examinations on the necessity of the regulations, their expected effects, and their projected costs, including the burden imposed by the regulation on the public.

E. **Access to Information:** The "Law Concerning Access to Information Held by Administrative Organs" came into effect on April 1, 2001. Furthermore, the Government of Japan submitted to the Diet in March 2001 the "Law Concerning Access to Information Held by Independent Administrative Institutions, etc. "(tentative translation), which is based on the Final Report of

July 2000 submitted by the "Investigation Committee on Access to Information Held by Public Corporations" (*Tokushu-hojin Joho Kokai Kento Iinkai*) under the Administrative Reform Promotion Headquarters. The legislation will provide the right to request the disclosure of information held by Independent Administrative Institutions (*dokuritsu gyosei hojin*), Public Corporations (*tokushu hojin*), and other corporations.

F. **Private Organizations:** The Government of Japan does not delegate to private organizations the authority for regulations that restrict the rights of, or impose obligations on, citizens, except where such delegation is expressly authorized by a law, a cabinet order or ministerial ordinance that is based on a law, or a local ordinance (*jorei*).

IX. LEGAL SYSTEM AND INFRASTRUCTURE

A. **The Judicial Reform Council:** The Government of Japan established the Judicial Reform Council under the Cabinet in July 1999 to clarify the function of the judicial system in the Japanese society in the 21st Century and to discuss the fundamental policies necessary to reform and provide the foundation for the judicial system. The Council issued its Interim Report in November 2000 and submitted its Final Report to the Cabinet on June 12, 2001. In the Final Report, the Council set out the following three primary themes and made comprehensive recommendations concerning reform of the judicial system:

1. Creation of a judicial system to meet the general public's needs and expectations;

2. Improvements in the legal profession that supports the judicial system; and

3. Promotion of public support for the judicial system.

B. **Legal Services (Cooperation between *Bengoshi* and *Gaikokuhou-Jimu-Bengoshi*)**

1. The Government of Japan recognizes that the demand for international legal services has significantly increased in Japan and that concerns have been expressed with regard to the sufficiency of the infrastructure of legal services capable of meeting the needs of international business. The Government of Japan also recognizes the importance of further promoting cooperation and collaboration between *bengoshi* and *gaikokuhou-jimu-bengoshi*.

2. Concerning the cooperation between *bengoshi* and *gaikokuhou-jimu-bengoshi*, the Final Report of the Judicial Reform Council recommended that:

   a. The Government of Japan should deregulate the requirements for specified joint enterprises (*tokutei kyodo jigyo*) from the viewpoint of further promoting

cooperation and collaboration between *bengoshi* and *gaikokuhou-jimu-bengoshi*; and

b. Concerning the reconsideration of the regulation that a *gaikokuhou-jimu-bengoshi* shall not employ a *bengoshi*, the Government of Japan should continuously study this issue as a future agenda item, while taking into account the development of international arguments.

C. **Judicial Reform Project Coordination Headquarters:** In order to consider specific measures to realize the Judicial Reform, and to take such necessary measures as aiming to enact relevant laws within three years, the Government of Japan is establishing a Judicial Reform Project Coordination Headquarters (Headquarters) in the Cabinet.

D. **Report of the Judicial Reform Council:** In its Final Report, the Judicial Reform Council recommended that the Government of Japan take significant steps to meet the needs of Japanese society in the 21st Century. The Government of Japan will expeditiously take measures to implement these recommendations. Among the recommendations are:

1. Increasing the number of legal professionals by:

a. Immediately taking necessary measures to increase the annual number of persons who pass the Bar Examination and aim to increase the annual number who pass to 1,500 by 2004; and

b. Seeking to increase the annual number of persons who pass the new Bar Examination to 3,000 by around 2010, depending upon how the new system for legal education and training, including the new law school system, is to be established.

2. Increasing the speed and efficiency of civil litigation by:

a. Reducing by half the length of time required to complete trials at courts of first instance;

b. Facilitating litigants' collection of evidence at early stages of litigation;

c. Promoting the efficient scheduling of hearings;

d. Increasing the number of judges; and

e. Improving the lawyers' ability to provide legal services;

3. Making the specialized departments concerning intellectual property rights at both the Tokyo and Osaka District Courts function substantially as "patent courts;"

4. Reducing filing fees for civil litigation;

5. Reforming the Arbitration Law; and

6. Undertaking a comprehensive study of judicial oversight over administrative agencies, including review of the Administrative Case Litigation Law.

E. **Access to Government Documents in Litigation:** In March 2001, the Government of Japan submitted a bill to the Diet that is aimed at extending the duty to produce documents, set out in Article 220 of the Code of Civil Procedure, to documents in the custody or possession of a public official, or a person who previously was a public official.

F. **Exchanging Views:** To further promote and facilitate cooperation and collaboration between *bengoshi* and *gaikokuhou-jimu-bengoshi*, the Government of Japan will continue to exchange views with the Japan Federation of Bar Associations (*Nichibenren*), the Foreign Lawyers' Association of Japan (*Gaikokuho-Jimu-Bengoshi Kyokai*) and the American Chamber of Commerce of Japan.

X. COMMERCIAL CODE

A. Legislative Council's Interim Report on Commercial Code Reform

1. In 2000, the Government of Japan commenced a major initiative to reform its Commercial Code.

2. The Corporate Law Division of the Legislative Council ("Council") of the Ministry of Justice (MOJ), on April 18, 2001, issued its Interim Tentative Draft of the Outline of Commercial Code Revision ("Interim Report"), which proposes major revisions to the corporate law system and invited comments on the draft from the public.

3. The Interim Report included recommendations to:

   a. Eliminate the restrictions on the recipients of stock options and on the quantity of stock options that a corporation can issue;

   b. Abolish the cap on issuance of new shares by closely-held corporations;

c. Permit classes of shareholders of closely-held corporations that have issued more than one class of shares to elect subsets of directors;

d. Raise the limit on non-voting shares to one-half of the total issued shares (from the current limit of one-third of total issued shares); and

e. Allow companies the option of dispensing with the statutory auditor (*kansayaku)* requirement, and adopting instead a corporate structure in which executive officers are specified, and audit, nomination and compensation committees are created, each of which must have a majority of outside directors.

4. After giving serious consideration to the public comments that were submitted on the Interim Report, it is scheduled that the Council will issue its final report on matters that are related to stock and Information Technology in September 2001, and its final report on all other matters in February 2002.

5. It is scheduled that the Government of Japan will submit to an extraordinary session of the Diet, which may be held in the latter half of 2001, a bill to revise certain aspects of the Commercial Code. The bill will include provisions addressing:

a. Revisions relating to the restriction on the range of people who may receive stock options and the quantitative restrictions on the issuance of stock options; and

b. Measures to make it possible to use the Internet or other electronic methods of transmission in the procedures which had been required to be completed by paper documents, such as the notice of shareholders' general meetings and the exercise of the right to vote on resolutions.

6. It is scheduled that the Government of Japan will submit a bill to the ordinary sessions of the Diet in 2002 that would make widespread amendments to the Commercial Code, based on the recommendations of the Council. This bill will include an amendment that will give corporations the choice of having audit committee and other committees and establishing executive officers, and in such cases the corporations would not be required to have auditors (*kansayaku*).

7. In addition to the introduction of the above-mentioned systems, the Government of Japan will consider necessary measures to strengthen the supervising function of directors' meetings, such as requiring one or more outside directors for certain types of corporations, and whether such measures should be introduced.

8. The Council, in light of concerns expressed by the international business community, will reevaluate its recommendation in the Interim Report that foreign corporations be required to appoint a registered representative who would be jointly and severally liable for all obligations of the corporation.

9. With respect to the public comments submitted on the Interim Report, MOJ will publish or otherwise make them available for public review, unless the party submitting the comments objects.

XI. DISTRIBUTION

A. Customs/Import Processing

1. Simplified Declaration Procedure**:** The Government of Japan has taken a number of steps to expedite import processing of goods into Japan, including the introduction of the Simplified Declaration Procedure. The Simplified Declaration Procedure was introduced in March 2001, which enables approved importers to have designated cargoes released prior to declarations for duty payments, by sending import declarations from duty payment declarations, with the condition of ensuring compliance of the relevant laws. The import declarations which use the Simplified Declaration Procedure started in April 2001.

2. Air-NACCS:

   a. The Nippon Automated Cargo Clearance System Operations Organization (NAACS Center) has been discussing with users the proposed user fee system of new Air-NACCS, which is scheduled for introduction in October 2001. These discussions started more than a year before the introduction of the system.

   b. The Center initiated a public comment procedure in March 2001 to gain further understanding among users and to ensure transparency in the procedures of designing the new fee system. Public comment was sought for such issues as the proposed user fee system, the principle of designing the user fee system, and the data of cost estimation. The Center posted these items on its website to seek comments from all users. The Center also posted a summary of the submitted comments and the Center's response to them on its website.

   c. The Center recognizes that the proposed user fee system is a major concern for users, and is also critical for stable operation of the Center, which seeks smooth operation of the system. Based on this recognition, the Center established a

committee in June 2001 to fully discuss the fee system among users. The committee includes representatives of users of the Air-NACCS system expecting cost increases, and will produce practical recommendations on the user fee structure on the system. The Center together with members of the committee expect to complete the committee's work and to fully address the recommendations before the introduction of the new Air-NACCS.

B. **Large-Scale Retail Stores (*Daiten Ricchi-Ho*: Law Concerning the Measures by Large-Scale Retail Stores for Preservation of the Living Environment) (the Law)**

The Ministry of Economy, International Trade and Industry (METI) will continue to take the following measures to facilitate the implementation of the Law in a consistent, transparent and predictable manner.

1. METI is monitoring local governments to ensure that they do not impede the purpose of the Law, and METI will continue to provide information regarding the application of the Law through meetings and technical training to the officials of local governments. METI will continue to provide local governments necessary information regarding the implementation of the Law and the role of the contact points.

2. METI will continue to receive and facilitate resolution of complaints from any interested party regarding the application of the Law through the contact points which were established last year.

C. **Competition in Sectors in Which Dominant Firms Control the Market:** The Government of Japan recognizes the economic benefits of increasing competition in the distribution sector. The Government of Japan confirms that making agreements among distributors or groups of distributors for the purpose of excluding imported or other competitors' products is detrimental to competition, and will violate the Antimonopoly Act. Therefore, the Government of Japan suggests that any enterprises or foreign governments notify the Japan Fair Trade Commission with specific information on any anticompetitive practices, if such exist, in any highly oligopolistic markets including the flat glass sector. METI will continue to pursue economic reforms to ensure competition in the distribution sector.

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

I. DEREGULATION, COMPETITION POLICY, AND OTHER MEASURES

A. Trade Related Issues

1. Hilmer Doctrine:

   a. The Government of the United States will continue to consider Japan's requests regarding the Hilmer Doctrine and other related issues under section 102(e) of title 35, United States Code, especially in the context of the ongoing substantive patent law harmonization talks taking place at the World Intellectual Property Organization in Geneva.

   b. The Government of the United States will continue to ensure full consideration of Japanese requests regarding the shift to a first-to-file system, further improvements of the early publication and re-examination systems, and adoption of the unity of invention rule in compliance with PCT practice.

2. Byrd Amendment:

   a. The Government of the United States and the Government of Japan had a series of discussions on the Byrd Amendment in the U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy through its fourth year dialogue from the viewpoint of the broad context of trade policy.

   b. The Government of the United States had consultations with the Governments of nine WTO members, including Japan, on the Byrd Amendment pursuant to Article 4 of the DSU, and Article XXII:1 of the GATT, in Geneva on February 6, 2001. The Governments of the nine members, including Japan, expressed their concerns to the Government of the United States regarding the consistency of the Byrd Amendment with WTO rules.

   c. The Government of the United States published proposed implementing legislation in the Federal Register on June 26, 2001. The Government of the United States will continue to exchange views with the Government of Japan regarding the Byrd Amendment.

3. Exon-Florio: The Government of the United States recognizes the Government of Japan's concern on the "Exon-Florio" clause regarding, inter alia, predictability of the regulations, legal stability of completed transactions, and ensuring due process. The Government of the United States has made an effort to respond to these concerns at meetings with the Government of Japan and through written responses to questions. In operating the clause, the Government of the United States is mindful of the Government of Japan's concerns, and will ensure the clause's consistency with WTO rules.

B. **Distribution**

1. Customs Clearance: The Government of the United States, in cooperation with the Government of Japan, will, by the end of calendar year 2001, work on a methodology to conduct a Time Release Survey that will be based on the Time Release Survey Guidelines developed by the WCO Permanent Technical Committee.

2. Licensing for Sales of Liquor: The Government of the United States has continued its dialogue with the California Department of Alcohol and Beverage Control on the issue of the treatment of Korean soju and Japanese shochu as addressed in the Business and Professions Code Section 23398.5. The California Department of Alcohol and Beverage Control has analyzed the express language of the statute and provides the following clarifications:

   a. Soju sold pursuant to this provision must be imported into the United States, be no more than 24 percent alcohol by volume, and be derived from agricultural products;

   b. While it must be imported, there is no further limitation on where soju may be produced or bottled;

   c. Contrary to prior advice, there is no statutory requirement that the label state that the product is "Korean" soju; and

   d. As to whether the Japanese word "shochu" may be used in place of the Korean word "soju" in the context of soju sold by on-sale beer and wine licensees pursuant to Business and Professions Code Section 23398.5, the section states that such licenses are authorized to sell "soju". There is no authority to use any alternate derivation or spelling of the word "soju".

C. **Consular Affairs**

1. The Government of the United States and the Government of Japan will continue discussions regarding measures that could address issues of concern related to consular affairs.

2. In general, the Government of Japan is welcome to use existing public comment procedures to make its views known regarding specific areas of U.S. immigration rules and regulations. Details may be found on the Department of Justice's Immigration and Naturalization Service web site at www.ins.usdoj.gov.

3. The Government of the United States is considering possible measures to improve the process and streamline overall procedures for obtaining H1-B visas. The Government of the United States established the Premium Processing Service for Employment-Based Petitions and Applications, which, if an entity pays the required fee, ensures INS will process the petition or application within 15 calendar days. INS plans to extend this service to H1-B applicants by July 30, 2001.

4. Regarding Arrival-Departure Records, or "I-94s", the INS is making efforts to reduce the processing period for applications to extend the period of permission to stay. As part of its ongoing Immigration Benefits Re-engineering program, the INS is also making efforts to streamline the processing of applications for extensions of stay. In addition, INS will consider measures to enable applications for extensions of stay to be accepted one year before the expiration of the I-94 and thereafter.

5. All lawful aliens in the United States, including Japanese citizens, are able to obtain a driver's license in all U.S. States and jurisdictions, provided they meet a state's driver license requirements. However, because most states require applicants to provide a Social Security Number (SSN) if they have one, an applicant who alleges not to have a SSN may be directed to the Social Security Administration (SSA) to apply for a SSN. In those states in which the applicant is ineligible for a SSN, SSA will promptly issue a letter so stating to the Japanese citizen applicant, which he/she can provide to the state licensing agency in lieu of a SSN.

6. Japanese citizens requiring a taxpayer identification number for financial and tax purposes, who are not eligible for SSNs, can apply for individual taxpayer identification numbers (ITIN) from the U.S. Internal Revenue Service (IRS). They may either visit the IRS in person or call the toll-free IRS number 1-800-TAXFORM (1-800-829-3676) and request form W-7, Application for an Individual Taxpayer Identification Number.

7. Many U.S. agencies and private businesses ask individuals for SSNs for many purposes, even from persons to whom SSA is not permitted by law to assign SSNs

and even when that information is not required to provide a requested service. For this reason, the SSA advises any Japanese citizen asked for an SSN, (who is not eligible for an SSN), to inform the agency or business that he/she does not have an SSN, and ask them to use another means of identification, for purposes of whatever service he/she requires. The SSA will inform those agencies and businesses of such ineligibility and instruct them to accept another means of identification. The SSA will consider establishing a contact point to register and respond to complaints from legal residents regarding SSNs.

8. SSA and the States will continue to provide information regarding State-specific processes and procedures for obtaining driver's licenses and other services and documents without a SSN.

D. **Legal Services:** In the United States, 23 States and the District of Columbia have foreign legal consultant rules. From the viewpoint of facilitating international business, the Government of the United States continues to support the adoption of such rules by the other States. The American Bar Association has been informed of the requests of the Government of Japan with respect to this issue.

E. **Product Liability Reform:** The Government of the United States recognizes that the Government of Japan has concerns regarding product liability reform, and will continue to exchange views with the Government of Japan concerning this issue. The Government of the United States confirms that it has no intention of treating foreign companies unfavorably in any product liability reform process.

F. **Competition Policy:** The Department of Justice will continue to review and express its views on the continued appropriateness of antitrust exemptions, and to seek the elimination of antitrust exemptions where warranted. Any public written expression of such views will be made available to the Government of Japan.

II. HOUSING

A. Codes/Standards

1. The Government of the United States continues to encourage local governments and relevant organizations to consider ISO protocols in the development and refinement of testing methods. Work is underway within the American Society for Testing Materials (ASTM) to enhance the language of certain ISO standards (e.g. ISO 834, ISO 1182) to facilitate reference and enforcement.

2. The Government of the United States has informed the evaluation bodies of the United States (e.g. ICBO Evaluation Service, Inc.) of the opportunities for mutual recognition with evaluation bodies in Japan.

3. The Government of the United States is supportive of the efforts underway by the International Code Council to develop the ICC Performance Code for Buildings and Facilities.

4. The Government of the United States and the Government of Japan will continue to have technical discussions on such issues as performance-based codes, implementation of test methodologies and procedures in evaluating fire-resistance.

B. **Adoption of Metric System:** The Government of the United States will continue measures to expand and increase the use of the metric system in the private sector and at the Federal and local government level. In the meantime, the United States has taken the following interim measures:

1. The National Institute of Standards and Technology (NIST) at the Department of Commerce and the National Conference on Weights and Measures (NCWM) coordinated regarding full implementation of the revised Uniform Packaging and Labeling Regulations (UPLR), which permit metric-only labeling on U.S. consumer products as of January 1, 2000.

2. A legislative proposal has been prepared for submission to Congress to update the Fair Packaging and Labeling Act (FPLA) to permit the option of metric-only labeling on products covered by the Act.

III. TELECOMMUNICATIONS

A. **Licensing in the U.S. Wireless Sector:** In response to the Government of Japan's concerns regarding restrictions on direct investment in carriers holding wireless licenses, the Government of the United States confirmed that foreign operators can and do hold radio licenses through 100 percent foreign-owned U.S. subsidiaries. The United States Government will continue a dialogue on this issue with the Government of Japan.

B. **Certification and Licensing of Foreign Carriers:** The United States Government will continue a dialogue with the Government of Japan relating to the transparency of U.S. certification and licensing criteria, including clarification of certain criteria and the application of dominant carrier regulations to carriers offering international service.

C. **Access to the U.S. Wireless Services Market:** The United States Government has taken into account concerns of trading partners, including Japan, related to proposed restrictions on investment in wireless licensees.

D. **State-Level Regulations:** The United States Government will continue a dialogue with the Government of Japan regarding state-level regulation, including licensing procedures, and the Government of Japan's interest in regulatory harmonization among states.

E. **Inter-State Access Charge:** The United States Government views the objective of using LRIC, or other regulatory policy tools, as ensuring that interconnection charges reflect the price that would be set in a competitive market. As a result of measures taken in the United States, charges for terminating inter-LATA calls declined substantially over the past several years. The United States Government will provide the Government of Japan information about the implementation of cost-based regulatory tools (including LRIC) at both the federal and state levels, information about participation in the CALLS access charge proposal, and information on judicial review of the LRIC methodology.

F. **Transparency in the Development and adoption of Costing Models:** The Federal Communications Commission (FCC) process for developing further LRIC models will continue to be through a transparent process incorporating public comments. Where the FCC adopts outside models, such adoption will also be subject to public comment.

G. **International Charging Arrangements for Internet Services:** This year, the U.S. National Academy of Sciences issued a report, "The Internet's Coming of Age," which discusses the direction of Internet development in this country. This report is available at www.nap.edu. Among other items, it concludes that the current level of monitoring of the Internet by the FCC and anti-trust authorities is appropriate and should continue. The United States Government has been and will be actively involved with Japan in APEC and ITU discussions of Internet-related matters, including participation in data-gathering exercises relating to the state of competition in the Internet.

H. **FCC Order Concerning the International Settlement Rate Benchmark:** The Government of the United States will continue to actively participate in multilateral fora seeking to address the issue of above-cost accounting rates, will contribute to credible efforts to resolve this issue, and will give due consideration to the development of the discussions in such fora.

IV. MEDICAL DEVICES AND PHARMACEUTICALS

A. **Good Manufacturing Practices:** The Food and Drug Administration (FDA) and the Ministry of Health, Labor and Welfare (MHLW) have actively worked toward a cooperative arrangement similar to a mutual recognition agreement regarding Good Manufacturing Practices

(GMPs.) In December of 2000, MHLW and FDA exchanged letters regarding cooperation in the exchange of pharmaceutical inspection reports and other pharmaceutical surveillance information. The letters include the intentions of both sides to:

1. Provide upon request copies of inspection reports and product sample test results;

2. Work on the development and maintenance of a joint inventory of pharmaceutical product manufacturing facilities located in Japan and the U.S., including a list of pharmaceutical products made at each facility;

3. Provide information on recalls of pharmaceutical products;

4. Respond to requests for other pharmaceutical product quality information; and

5. Review the progress and benefits of the information exchange and meet at least once every three years to discuss this exchange.

FDA continues to work with MHLW through exchanges of information and other cooperative activities regarding GMPs for medical devices. The FDA and MHLW recognize the importance of these activities. The cooperative process will be pursued and further technical discussions will be continued.

B. **Good Clinical Practices:** FDA will continue cooperative activities regarding Good Clinical Practices (GCPs) especially in the ICH fora, and FDA will continue to respond appropriately to foreign regulatory bodies' requests, including MHLW's, for information regarding GCPs. When MHLW staff come to the U.S. FDA may provide opportunities to exchange information.

C. **Data Requirements for Change in Color of Pharmaceuticals:** FDA confirms that the requirement for bioequivalence studies for color changes can be waived on a case-by-case basis.

D. **Export Certification Requirements:** FDA has published a proposal in the Federal Register that will (among other things) allow a responsible company official in the U.S. to certify that the export of an unapproved FDA-regulated product does not conflict with a foreign country's laws.

E. **Medical Device GMP Inspections:** As a general rule, FDA does not inspect suppliers of raw materials and components for medical devices. The Quality System Regulation requires medical device manufacturers to evaluate their suppliers for their ability to supply components that meet the device manufacturer's specifications and quality requirements. The FDA does not specifically require that manufacturers evaluate suppliers by inspecting them.

F. **Cosmetic Color Regulation:** For those colors used in cosmetics that are listed in FDA's Permanently Listed Cosmetic Color Additives and Provisionally Listed Cosmetic Color Additives subject to certification, each batch of synthetic color additive must be certified by FDA. The cosmetic company is exempted from submitting the color additive to FDA for certification provided that the company uses a color additive batch that has been certified by FDA.

V. FINANCIAL SERVICES

A. Banking

1. Financial Holding Company Requirements: The Gramm-Leach-Bliley ("GLB") Act requires capital and management standards for a foreign bank that are comparable to the standards applied to a U.S. bank owned by a financial holding company (FHC), giving due regard to the principle of national treatment and equality of competitive opportunity. The standards are applied to all foreign banks on a nondiscriminatory basis. The Board issued a final rule regarding the criteria and procedures for being a FHC. The leverage ratio was removed from the screening test used to determine whether a foreign bank satisfies the well-capitalized standard. The screening test now references only tier 1 and total capital levels calculated under the Basel Capital Accord. The Board will continue to consider a foreign bank's leverage ratio as one of the factors in determining whether a foreign bank has capital comparable to a well-capitalized U.S. bank.

2. Section 20 Companies: With respect to so-called "section 20" companies, the United States applies capital standards that are fully consistent with the Basel Capital Accord. These capital levels apply equally to U.S. and foreign banking organizations, consistent with national treatment. Consistent with prudential requirements, the Board is required to evaluate the overall financial condition of any applicant including all relevant factors, such as capital, profitability, concentrations of risk, liquidity, asset quality, and the adequacy of loan loss reserves.

3. Capital Equivalency Deposit: Repurchase agreements are now excluded from the liabilities against which assets must be pledged in New York. The New York State Banking Department has asked foreign banks to identify other instruments that share characteristics of repurchase agreements and therefore can be excluded from the liabilities against which assets must be pledged.

B. Securities

1. Notification Requirements on Securities Offered Outside the U.S.: The SEC historically has recognized that the registration of public offerings of securities with only incidental contacts with the United States should not be required. The SEC adopted Regulation S in 1990 in order to clarify the extraterritorial applicability of the registration requirements under the Securities Act of 1933. Any offer, offer to sell, sale, or offer to buy of securities that occurs outside the United States is not subject to the Securities Act's registration requirements. The determination as to whether a transaction occurs outside the United States is based on the facts and circumstances of each case. Regulation S also provides non-exclusive safe harbors the benefits of which are subject to specific procedures.

2. "Blue Sky" Memo: In October 1996, the National Securities Markets Improvements Act amended the Securities Act of 1933 to provide for federal preemption of state laws and regulations requiring registration of securities in many cases. As a result, the need to register securities at the state level has been eliminated in connection with most significant securities offerings in the United States, including those by non-U.S. issuers. However, the states preserve the authority to administer and enforce their own anti-fraud laws.

3. Advertising Restrictions on Global Offerings: An issuer that is preparing to sell securities in the United States is able to communicate ordinary-course business and financial information with the public. In addition to giving guidance in this area, the SEC has adopted many rules that allow for certain communications to be made in connection with an offering of securities after a registration statement has been filed with the SEC (see, for example, rules 134 and 135 of the Securities Act of 1933). Moreover, Rule 135e under the Act provides a safe harbor for offshore press communications by foreign issuers with respect to cross-border offerings.

4. Exemption from Investment Company Act (1940): There are a number of exemptions available under the Investment Company Act of 1940 that exclude certain issuers from the definition of investment company (see Sections 3(b)(1) and 3(b)(2) of the 1940 Act and Rules 3a-1 through 3a-7 thereunder).

5. Treatment of JGB in Capital Adequacy Ratios: There is little difference in the treatment of GOJ debt versus U.S. government debt for purposes of the SEC's net capital rule. The New York Stock Exchange has proposed amendments to its margin rule (Rule 431) that would lower the margin requirements for foreign sovereign debt securities that are rated in the top two ratings of a Nationally Recognized Statistical Rating Organization. The amendments are currently under review by the SEC.

6. Allowing Stabilization Operations on Global Offerings: In 1999, the SEC granted an exemption for global offerings of Japanese securities, whereby the Japanese stabilization rules would apply after the U.S. tranche of the offering has been completed. Syndicate stabilizing operations in Japan before the U.S. tranche of the offering is completed must comply with Rule 104 of Regulation M of the Securities Exchange Act of 1934. Rule 104 does, however, offer an avenue to allow off-shore stabilization during a U.S. offering without following the U.S. stabilization rule subject to three conditions: 1) there can be no stabilization in the United States; 2) no stabilization can be conducted above the U.S. offering price; and 3) the foreign stabilization must be conducted in a jurisdiction with "comparable" regulation of stabilization.

7. Criteria for Authorizing Ratings Agencies: To enter the U.S. market, a foreign rating agency is not required to be registered or designated as a Nationally Recognized Statistical Rating Organization ("NRSRO") by the SEC. Instead, SEC staff has taken no-action positions with respect to the treatment by broker-dealers of certain rating agencies as NRSROs for net capital purposes. In issuing no-action letters with respect to NRSRO treatment, SEC staff relies upon the marketplace to have previously judged the credibility of an institution's ratings.

8. Registration Requirement for Newly Issued Foreign Bonds: Foreign governments may be able to bypass both registration requirements under the Securities Act of 1933 (Schedule B) and the 40-day waiting period by taking advantage of exemptions in the Act that apply to certain types of securities transactions. See, for example, Section 4(2) of the Securities Act; see also description from the Third Joint Status Report.