Common Technical Document (CTD) and possibilities for new topics. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Group meetings in Tokyo, Japan, May 21 to 24, 2001, at which discussion of the CTD and possible new topics will be continued.

Date and Time: The public meeting will be held on May 8, 2001, 10:30 a.m. to 2 p.m.

Location: The public meeting will be held at 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

Contact: Kimberly Topper, Center for Drug Evaluation and Research, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852, 301–827–7001, FAX 301–827–6801, or email: Topperk@cder.fda.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations to the contact person by May 1, 2001.

If you need special accommodations due to a disability, please contact Kimberly Topper at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

The International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. The ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations. The ICH Steering Committee includes representatives from each of the ICH sponsors and Canadian Therapeutics Programme, and the European Free Trade Area. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions. The current ICH process and structure can be found on the Internet at http://www.ifpma.org/ich1.html.

II. Issues To Be Discussed at the Public Meeting

The issues to be discussed include the following: (1) ICH overview and procedures, (2) CTD, and (3) possibilities for new topics (e.g., biotech and postmarketing surveillance).

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 2 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by May 1, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be available on May 2, 2001, at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, under Docket Number 01N-0167.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: April 18, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–10068 Filed 4–23–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Exchange of Letters Between the Food and Drug Administration and Japan Concerning the Exchange of Certain Information on Pharmaceutical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of an exchange of letters between FDA, Department of Health and Human Services, United States of America and the Inspection and Guidance Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health and Welfare, Japan. The parties concluded this exchange of letters on December 27, 2000. These letters express the intentions of the United States and Japan to exchange information on matters useful to preserving the safety, quality, and efficacy of pharmaceutical products in the markets of the United States and Japan.

DATES: Cooperation under the exchange of letters began December 27, 2000.

FOR FURTHER INFORMATION CONTACT: Joseph Famulare, Division of Manufacturing and Product Quality (HFD–320), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–827–0590.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this exchange of letters.

Dated: April 11, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

BILLING CODE 4160–01–S

Ministry of Health and Welfare
1-2-2, Kasumigaseki, Chiyoda-ku, Tokyo, 100-8045 Japan
TEL:+81-3-3595-2436 FAX:+81-3-3503-1043

December 22, 2000

Ms. Sharon Smith Holston
Deputy Commissioner for International and Constituent Relations
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
United States of America

Subject: Exchange of Certain Information on Pharmaceutical Products

Dear Ms. Holston:

This letter concerns cooperation in the exchange of pharmaceutical inspection reports and other pharmaceutical surveillance information between the Inspection and Guidance Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health and Welfare (MHW), Japan, and the Food and Drug Administration (FDA), United States of America.

MHW would like to begin exchanging inspection reports and surveillance information on pharmaceutical products. "Pharmaceutical products" means those products that are defined as "drugs for human use" in both countries and to which Good Manufacturing Practice (GMP) requirements of the respective countries are applied. The definition of "pharmaceutical products" includes active ingredients. Recognizing this information sharing as an initial step to expand cooperative activities and enhance understanding of each other's systems, the Inspection and Guidance Division, MHW intends to:

1. Provide upon request copies of inspection reports and product sample test results describing the conformity of a pharmaceutical product manufacturing facility located in Japan to MHW's current GMP requirements.

2. Restrict to information which is already routinely collected and maintained for pharmaceutical products which have already been approved for marketing and distributed in the importing country.

3. Exclude information collected as part of a pre-marketing approval evaluation process.

4. Work with FDA 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.

5. Provide information on MHW-classified recalls of pharmaceutical products known by MHW to have been manufactured or distributed in the U.S.

6. Respond to FDA requests for other pharmaceutical product quality information. Provide such information when able to do so or explain why such information cannot be provided.

7. Provide all communications in English.

8. Protect any information received from FDA to the extent permitted by Japanese laws and regulations and provide FDA with copies of Japanese laws and regulations governing MHW's ability to maintain information as confidential.

9. Generally provide all information described above in a manner fit for public dissemination under Japanese laws and regulations. MHW will consider providing specifically requested non-public information only in accordance with established Japanese laws and regulations.

10. Welcome FDA officials where appropriate for the purpose of studying the implementation of the MHW GMP regulatory system, as resources permit.

11. Appoint a liaison(s) for the exchange of information and other communications made between MHW and FDA. The MHW liaison(s) will notify the designated FDA liaison(s) of any concerns or problems with the provided information described in this letter and work diligently to resolve these as well as all FDA concerns.

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

All activities described in this letter are to be carried out consistent with the laws and regulations applicable to each country.

MHW intends to provide three months notice to FDA before ceasing or changing any of these activities. If these activities are to be changed, MHW intends to review those changes, consulting with the Ministry of Foreign Affairs.

Please let us know at your earliest convenience whether these intentions are acceptable to FDA.

Sincerely yours,

Jun'ichi SHIRAISHI
Director,
Inspection and Guidance Division
Pharmaceutical and Medical Safety Bureau
Ministry of Health and Welfare

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

December 27, 2000

Mr. Jun'ichi Shiraishi
Director
Inspection and Guidance Division
Pharmaceutical and Medical Safety Bureau
Ministry of Health and Welfare
Japan

Subject: Exchange of Certain Information on Pharmaceutical Products

Dear Mr. Shiraishi:

The U.S. Food and Drug Administration (FDA) recognizes the importance of timely communication between U.S. and Japanese governmental authorities on matters useful to preserving the safety, quality, and efficacy of pharmaceutical products in the markets of the United States and Japan. FDA has high regard for the critical role of the Japanese Ministry of Health and Welfare (MHW) in the collection and use of information about pharmaceutical products manufactured and distributed in Japan. The intentions expressed in your letter of December 22 are acceptable to FDA. "Pharmaceutical products" means those products, including active ingredients, that are defined as "drugs for human use" in both countries and to which Good Manufacturing Practice (GMP) requirements of the respective countries are applied. The definition of pharmaceutical products above includes active ingredients.

By this letter FDA intends to:

1. Provide upon request copies of inspection reports and product sample test results describing the conformity of a pharmaceutical product manufacturing facility located in the U.S. to FDA's current GMP requirements.

2. Restrict to information already routinely collected and maintained for pharmaceutical products which have already been approved for marketing and distributed in the importing country.

3. Exclude information collected as part of a pre-marketing approval evaluation process.

4. Work with MHW 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.

5. Provide information on FDA-classified recalls of pharmaceutical products known by FDA to have been manufactured or distributed in Japan.

6. Respond to MHW requests for other pharmaceutical product quality information. Provide such information when able to do so or explain why such information cannot be provided.

7. Permit MHW access to FDA's GMP compliance status database for U.S. pharmaceutical manufacturing facilities.

8. Protect any information received from MHW to the extent permitted under FDA regulation (Title 21, Section 20.89 of the U.S. Code of Federal Regulations) and provide MHW with copies of U.S. laws and regulations governing FDA's ability to maintain information as confidential.

9. Generally provide all information described above in a manner fit for public dissemination under U.S. laws and regulations. FDA will consider providing specifically requested non-public information only in accordance with established U.S. laws and regulations.

10. Welcome MHW officials where appropriate for the purpose of studying the implementation of the FDA GMP regulatory system, as resources permit.

11. Appoint a liaison(s) for the exchange of information and other communications between FDA and MHW. The FDA liaison(s) will notify the designated MHW liaison(s) of any concerns or problems with the provided information described in this letter and work diligently to resolve these as well as all MHW concerns.

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

All activities described in this letter are to be carried out consistent with the laws and regulations applicable to each country.

FDA intends to provide three months notice to MHW before ceasing or changing any of these activities. If these activities are to be changed, FDA intends to review those changes, consulting with the Department of State.

Mr. Jun'ichi Shiraishi--Page 3

It is my hope that this letter will serve to enhance the continued beneficial and productive relationship between the MHW and the FDA. FDA looks forward to a future time when both governments are ready to build further on the feelings of trust and cooperation that have led to the cooperation described in this letter.

Sincerely,

Sharon Smith Holston
Deputy Commissioner
for International and Constituent Relations

[FR Doc. 01–10017 Filed 4–23–01; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4653–05]

Notice of Proposed Information Collection for Public Comment: Notice of Funding Availability and Application for the Tribal Colleges and Universities Program

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* June 25, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name or OMB Control Number and be sent to: Reports Liaison Officer, Office of Policy Development and Research, U.S. Department of Housing and Urban Development, 451 7th Street, SW, Room 8226, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Jane Karadbil, Office of University Partnerships—telephone (202) 708–1537. This is not a toll-free number. Copies of the proposed forms and other available documents to be submitted to OMB may be obtained from Ms. Karadbil.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected entities concerning the proposed information collection to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of information to be collected; and (4) Minimize the burden of collection of information on those who are to respond; including through the use of appropriate technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of the Proposal: Notice of Funding Availability and Application Kit for the Tribal Colleges and Universities Program (TCUP).

Description of the need for the information and proposed use: The information is being collected to select grantees in this statutorily-created competitive grant program. The information is also being used to monitor the performance of grantees to ensure that they meet statutory and program goals and requirements.

Members of the affected public: Tribal colleges and universities seeking assistance to build, expand, renovate, and equip their own facilities.

Estimation of the total number of hours needed to prepare the information collection including the number of respondents, frequency of response, and hours of response: Information pursuant to submitting applications will be submitted once. Information pursuant to grantee monitoring requirements will be semi-annually and at the completion of the grant.

The following chart details the respondent burden on an annual basis:

	Number of respondents	Total annual responses	Hours per response	Total hours
Application	32	32	80	2,560
Semi-annual reports	9	18	16	288
Final reports	9	9	16	144
Recordkeeping	9	9	24	216
				3,208