

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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**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.

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**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  
April 11, 2001.

*Ann M. Witt*

Ann M. Witt,  
Acting Associate Commissioner for Policy.

[INSERT LETTERS]

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

*Jan Anderson*



## Ministry of Health and Welfare

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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

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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.

Mr. Jun'ichi Shiraishi--Page 2

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.

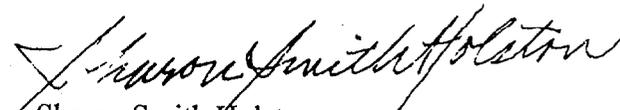
All activities described in this letter are to be carried out consistent with the laws and regulations applicable to each country.

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.

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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,

A handwritten signature in cursive script, reading "Sharon Smith Holston". The signature is written in dark ink and is positioned above the printed name.

Sharon Smith Holston  
Deputy Commissioner  
for International and Constituent Relations