



DEPARTMENT OF HEALTH AND HUMAN SERVICES

U.S. Food and Drug Administration
Office of the Commissioner
Silver Spring, Maryland
USA - 20993

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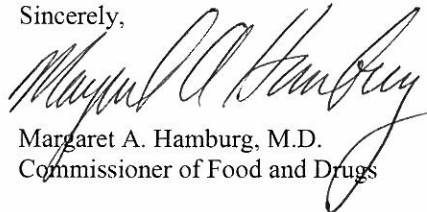
Dear Professor Tominaga:

It is with great pleasure that I award you the U.S. Food and Drug Administration's (FDA) Commissioner's Special Citation Award in honor of your outstanding dedication to fostering collaboration between Japan's Pharmaceutical and Medical Devices Agency (PMDA) and the FDA and for superior leadership in the International Conference on Harmonization (ICH) initiative for many years. Both of these efforts have clearly resulted in better promotion and protection of public health in Japan and the United States of America and have helped both agencies better align themselves as part of the greater global pharmaceutical regulatory community.

For close to a decade, you were an integral, highly active, and contributory part of building and strengthening both the FDA-PMDA bilateral relationship and the ICH initiative – especially in your long-standing role on the ICH steering committee. Any successes we have had in both ICH and the bilateral relationship with PMDA (including over 50 agreed ICH guidances, 7 FDA Mansfield fellows working in Japan – and always working partially with PMDA – for a year, and your coming to the FDA and working with us for a year) would not have been possible without your input and leadership. Because of your incredible facility with the English language (even making witty jokes and pithy puns) and your keen understanding of the scientific and regulatory process issues that confronted all of us, you were the international “face and voice” of PMDA and the best window for most of us into your organization. Through your secondment at the FDA you were able to learn about our processes and the ways in which we approach issues in a way that only such an experience affords. Of your many attributes, not only your scientific skills, but also your quick mind and language literacy served PMDA, FDA, and the rest of the global pharmaceutical regulatory community extremely well. You were not only able to make your organization understandable to the rest of us, you were the one who so often was able to make our organization, ideas, and processes understandable to our PMDA colleagues.

For being the cultural, linguistic, scientific, and process “bridge” between PMDA and FDA for well over a decade, for your dedication to building a stronger PMDA-FDA bilateral relationship, and for the integral part you played in so many successful outcomes from the ICH initiative, with much gratitude on behalf your colleagues at the FDA, I am delighted to bestow this award on you and to offer you heartiest congratulations on receiving the FDA Commissioner's Special Citation Award.

Sincerely,



Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs