To: CN=Jared G Kerr/OU=AM/O=LLY@Lilly

**Date:** 04/12/2002 08:00:00 AM

From: CN=Patrizia Cavazzoni/OU=AM/O=LLY

Subject: MHLW PI

**Attachments:** Revision Draft by MHLW on April 12 .doc

**Jared** 

THis is self-explanatory. Call me on my cell when you get in

## Patrizia

---- Forwarded by Patrizia Cavazzoni/AM/LLY on 04/12/2002 06:41 AM -----

## **Andrew Mascarenhas**

04/12/2002 04:58 AM

Michael E Bandick/AM/LLY@Lilly, Charles M Beasley Jr/AM/LLY@Lilly, Alan Breier/AM/LLY@Lilly, Patrizia

Cavazzoni/AM/LLY@Lilly, Melissa Lucke Halkyard/AM/LLY@Lilly, John C Lechleiter/AM/LLY@Lilly, Matthew R

Pike/AM/LLY@Lilly, Andrea K Smith/AM/LLY@Lilly, Gary D Tollefson/AM/LLY@Lilly, Denice M

Torres/AM/LLY@Lilly

CC:

To:

Subject: MHLW PI

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ladies and gentlemen: after the meeting with the outside panel of safety experts, this is the text of the PI that the MHLW has given us to incorporate. as you can see this is equal or worse than the 'worst case scenario' and almost identical to the language that the MHLW had started off on the 1st day of negotiations.

what remains to be done at the japan end is as follows:

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- 1. we have to confirm the text and ensure that the japanese is correct. while all the local advice is against it, we are contacting them to suggest a small change in the warnings section re blood glucose monitoring.....the chances are close to zero but may be worth the risk
- 2. the text of a 'dear doctor' letter is to be sent to the MHLW.....they had earlier said that the text would need to be agreed on monday...vague in timing...in a best case, we may be able to delay the mandatory press conf to a tue....but there is a possibility that this could be as soon as monday PM...in which case, it could hit the US/EU newswire in the morning of mon and i realize what impact this could have in the context of the annual shareholders mtg.

will talk to you bert in a few mins...regards-andrew

---- Forwarded by Andrew Mascarenhas/AP/LLY on 04/12/2002 06:36 PM -----

## Yasushi Ito

04/12/2002 04:55 PM To: Albertus vandenBergh/AM/LLY@Lilly

cc: Andrew Mascarenhas/AP/LLY@Lilly, Andrew J Wood/AP/LLY@Lilly, Sachiko Konaka/AP/LLY@Lilly, Noriko

Akagi/AP/LLY@Lilly

Subject: MHLW PI

Please see attached.

Yashi

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