From: OC GCP Questions
To: [redacted]
Cc: Budashewitz, Philip; Garcia, Edmundo;
Subject: INVITATION TO PARTICIPATE IN BIOTECHNOLOGY WORKSHOP
Date: Thursday, September 10, 2015 5:45:39 AM

Good morning [redacted]–

Janet is out of the office today. Please see the information below from our Office of International Programs. They are asking that you contact FDA's Latin America Office directly. Their contact information is below.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Wednesday, September 09, 2015 4:57 PM
To: OC GCP Questions;
Cc: Kezer, Doreen M; Budashewitz, Philip; Garcia, Edmundo
Subject: RE: INVITATION TO PARTICIPATE IN BIOTECHNOLOGY WORKSHOP

Hi Janet and my apologies for the delay. Since this involves Chile, please have the inquirer contact our Latin America Office directly. Information on our Latin America Office is below. Edmundo/Phil, FYI and please don't forget to cc: the GCP general mailbox.

Edmundo Garcia
Director
Philip M. Budashewitz
Deputy Director
More about the Latin America Office
San Jose website

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E-mail: **US-FDA-LAO@fda.hhs.gov**

U.S. Food and Drug Administration
Office of International Programs
Latin America Office
U.S. Embassy
Ave 0, Calle 120
Frente al Centro Comercial del Oeste
Rohrmoser, Pavas, Costa Rica

From: [redacted]
Sent: Friday, September 04, 2015 1:59 PM
To: OC GCP Questions
Cc: [redacted]
Subject: INVITATION TO PARTICIPATE IN BIOTECHNOLOGY WORKSHOP
Importance: High

To whom it may concern,

First let me introduce myself. My name is [redacted]

I would like to give you a little background about this email. We are planning a public – private public mission to Washington DC and Boston the last week of October.

The subject of the mission is Biotechnology in Life Science and our main goal is to bring Chilean companies and representatives from public and private sector as well as academia to learn about the industry and its regulatory framework .

We are working closely with the Chilean embassy in Washington D.C. (copied here) and other relevant actors of the Government in Chile, such as the Public Institute of Health and the Ministry of Economy and the Chilean Agency for Economic Development (CORFO by its acronym in Spanish) We are meeting different organizations and institutes in Washington D.C. such as BIO, USPTO and NIH but we are especially interested in meeting with the FDA to learn about international harmonization of clinical trails' best practices. This is an important topic that we would like to address because of the current discussion among the Chilean stakeholders and regulatory entities.

In this regard, we would be pleased if the FDA could participate in our first workshop where we will address the US regulatory framework in collaboration with BIO and USPTO. This activity will take place at the Embassy of Chile on October 26, 2015.

Please do not hesitate to contact me about any question you may have about this activity.

Sincerely,

[redacted]