From: Toth-Allen, Jean
Sent: Wednesday, December 27, 2006 10:29 AM
To: [Redacted]
Subject: RE: HELP IN OBTAINING CERTIFICATES OF CONFIDENTIALITY

[Redacted],

The proper individual at FDA to contact varies with the nature of the product under investigation - i.e., whether the investigational product is a drug, biologic, or device.

For **investigational drugs** the contact is:

Julie Unger
Division of Scientific Investigations (HFD-45)
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
7520 Standish Place
Rockville, MD 20855
Phone #: 301-827-1685
FAX: 301-594-1204
E-mail: julie.unger@fda.hhs.gov

For **investigational biologics** the contact is:

Patricia Holobaugh (HFM-664)
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MDS 20852
Phone #: 301-827-6347
FAX: 301-827-6748
E-mail: patricia.holobaugh@fda.hhs.gov

For **investigational devices** the contact is:

Sheila Anne Brown
Investigational Device Exemptions Staff (HFZ-403)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850
Phone #: 240-276-4034
FAX: 240-276-4009
E-mail: sheila.brown@fda.hhs.gov

While there are many people out on use it or lose it leave, a call will either reach a secretary or an out-of-office voice mail message. In either case, this should lead to whomever is filling in during that person's absence and who can probably provide the proper information. Hopefully [Redacted] will have better luck working through the direct contact responsible for the study in question.

Jean

From: [Redacted]
Sent: Friday, December 22, 2006 4:07 PM
To: [Redacted]
Cc: [Redacted]
Subject: HELP IN OBTAINING CERTIFICATES OF CONFIDENTIALITY

Dear [Redacted]:

[Redacted]

I am writing to you to ask for assistance. [Redacted] has reviewed several studies that involve taking urine samples from subjects that are likely to contain traces of illicit drugs. The IRB feels obligated to make sure that every effort will be made to protect the confidentiality for the subjects. For that reason the IRB has stipulated that the project cannot be initiated until a Certificate of Confidentiality (CoC) has been obtained to protect the specimens and data gathered in these studies.

The PI has requested of CoC from NIH, but because the studies involve FDA regulated products, NIH instructed the PI to seek a CoC from FDA. FDA has not responded. In several cases the PIs have abandoned the studies because FDA takes so long. Can you identify a person or an office at FDA that will issue CoCs promptly? If you can help us, it will greatly facilitate the conduct of several worthwhile studies that are delayed for want of a CoC.

Best wishes for a joyous holiday season,

[Redacted]