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Envelope-to: hammond@ud04.underdoghosting.com
Subject: RE: COMPLAINT: Meridian Biosciences
Date: Tue, 10 Apr 2007 07:35:04 -0400
Thread-Topic: COMPLAINT: Meridian Biosciences
Thread-Index: Acd67w5zPGZ41ub9QjCNNMg7Q/eOqQAdQxWw
From: "Shipp, Allan \(NIH/OD\) [E]" <ShippA@OD.NIH.GOV>
To: "Edward Hammond" <hammond@sunshine-project.org>
Cc: "Patterson, Amy \(NIH/OD\) [E]" <PattersA@OD.NIH.GOV>,

"Bonham, Valerie \(NIH/OD\) [E]" <BonhamVa@mail.nih.gov>
Dear Mr. Hammond,
This is to acknowledge receipt of your April 9, 2007 email regarding
Meridian Biosciences. We will look into the facts pertinent to your
complaint and determine an appropriate response.
Thank you for bringing this matter to our attention.
Allan Shipp
NIH Office of Biotechnology Activities
301-435-2152
----Original Message----
From: Edward Hammond [mailto:hammond@sunshine-project.org]
Sent: Monday, April 09, 2007 5:35 PM
To: Patterson, Amy (NIH/OD) [E]; Bonham, Valerie (NIH/OD) [E]; Shipp,
Allan (NIH/OD) [E]
Subject: COMPLAINT: Meridian Biosciences
Dear Dr. Patterson:
By this e-mail I submit a formal complaint against the IBC of
Meridian Biosciences. I request that NIH immediately terminate all funding to Meridian (and its subsidiaries, includding that producing
reagents for BEI Resources).
Meridian's minutes are obviously noncompliant. They obviously have no
functional IBC.
I look forward to hearing from you in this matter.
I am also awaiting a reply to the e-mail below.
Sincerely,
Edward Hammond
____
At 11:29 AM -0700 4/3/07, Edward Hammond wrote:
                 I should also have pointed out that this research is
>My apologies.
>NIH-funded.
>EH
>>Date: Tue, 3 Apr 2007 11:26:46 -0700
>>To: "Shipp, Allan \(NIH/OD\) [E]" <ShippA@OD.NIH.GOV>
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SOURCE: IBC Archive | The Sunshine Project - FOI Fund | www.sunshine-project.org



3471 River Hills Drive Cincinnati, Ohio 45244 Telephone: 513.271.3700 www.meridianbioscience.com

Mr Edward Hammond Director US Office of the Sunshine Project PO Box 41987 Austin TX 78704

E-mail: <u>Hammond@sunshineproject.org</u>

March 6, 2007

Dear Mr Hammond:

I am Chairman of the Institutional Biosafety Committee at Meridian Bioscience, Inc. I have been informed by the Office of Biotechnology Activities, National Institutes of Health (NIH) that your organization has requested minutes of Institutional Biosafety Committee (IBC) meetings for Meridian Bioscience, Inc. (Cincinnati, OH). I am responding to this request.

Enclosed is a copy of the minutes of our Biosafety Committee meeting, which was held June 2, 2005. This document is on file with the NIH. At present Meridian Bioscience, Inc. is not conducting any recombinant DNA research funded through NIH support. Please note that prior to this meeting, Meridian's NIH grant support expired. We have conducted no additional IBC meetings since that time since they are no longer required.

In the future, please address all correspondence concerning IBC activities to me, with CC to: Ms Susan Rolih, VP for Regulatory Affairs and Quality Assurance and Mr Ken Kozak, VP for Research & Development, at Meridian's address.

Thank you for your attention.

Sincerely,

K John Morrow, Jr, PhD

Chair

Institutional Biosafety Committee

Meridian Bioscience, Inc 3471 River Hills Drive

Cincinnati, OH 45244



## Memorandum

Date: August 3, 2005

To: Michelle Johnson
IBC Coordinator
National Institutes of Health
Office of Biotechnology Activities
6705 Rockledge Dr., Suite 750
Bethesda, MD 20892-7985
Email: JohnsoM1@od.nih.gov

From: John Morrow

Subject: Institutional Biosafety Committee report

A first organizational meeting of the Meridian Bioscience, Inc. (MBI), Institutional Biosafety Committee was held on Thursday, the 2<sup>nd</sup> of June for the purpose of setting guidelines and discussing the function of the committee.

The present committee is composed of eight members, including two outsiders, in conformance with guidelines established by the NIH. The meeting was attended by: Ken Kozak, VP for R&D, MBI; Melissa Colbert, Chair, Cincinnati Children's Hospital IBC; Dorothy Elsaesser, Cincinnati Children's Hospital IBC Safety Officer; Peter Condon, Senior Scientist, MBI; Jeff Kraft, Senior Scientist, MBI; James Deng, Senior Scientist, MBI; Susan Rolih, VP for Regulatory Affairs, MBI; and John Morrow, Chair of the MBI IBC.

The committee was formed in order to bring Meridian Bioscience, Inc., into compliance with NIH regulations regarding the oversight of research involving recombinant DNA. The guidelines state that institutions that receive NIH support must have oversight of their activities by an IBC. The committee must meet periodically and review those projects (including those not funded by NIH) involving recombinant DNA research. The roster of the participants and their CVs are appended to this document.

It was decided that the MBI/IBC will deal exclusively with issues concerning recombinant DNA research, since other regulatory

responsibilities involving the CDA, USDA and FDA are covered by regulatory committees that are already in place.

We will be meeting again in the near future to review those proposals that involve the use of recombinant DNA.

1977 - 2007

3471 River Hills Drive Cincinnati, Ohio 45244 Telephone: 513.271.3700 www.meridianbioscience.com

Ms. Michelle Johnson-Lancaster IBC Coordinator
Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive
Suite 750 MSC7985
Bethesda MD 20892-7985

March 1, 2007

Dear Ms. Johnson-Lancaster:

This letter is in response to the letter of the 20th of February to Meridian sent to me by Dr. Patterson. This letter concerns a complaint on the part of the Sunshine Project, of which Mr. Edward Hammond is the Director. The complaint indicates that Meridian was unresponsive to a 2006 request for copies of the company's Institutional Biosafety Committee (IBC) meeting minutes.

We will be happy to comply with Mr. Hammond's request in accord with NIH rules and regulations, which permit the redacting of proprietary information in such correspondence.

Thank you for bringing this matter to our attention.

Sincerely,

K. John Morrow, Jr., PhD

Senior Consultant Chairman, IBC

CC: Edward Hammond, Director, The Sunshine Project