



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive  
Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive  
Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 402-7065

August 17, 2018

Re: Animal Welfare Assurance  
A4614-01 [OLAW Case K]

Dr. Gregory Kelly  
Senior Vice President  
SoBran, Inc.  
4000 Blackburn Lane, (b) (4)  
Burtonsville, MD 20866

Dear Dr. Kelly,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of a letter dated August 14, 2018 reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Sobran BioScience. Your letter supplements the prompt telephone report received by this office on February 16, 2018. According to the information provided, OLAW understands that veterinary rounds were not conducted at the Rangos facility during the month of December 2017. Once discovered, a backup veterinarian was called in to perform animal health rounds. The responsible veterinarians no longer work in any capacity for SoBran and extra quality assurance checks have been implemented by the facility staff to ensure this does not happen again.

OLAW believes that the corrective and preventative measures put in place by Sobran BioScience are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of this incident and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



SoBran  
BioScience

August 14, 2018

Axel Wolff, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Dear Dr. Wolff:

SoBran BioScience, a division of SoBran, Inc., with Assurance #A4614-01, in accordance with PHS Policy IV.F.3., any serious or continuing noncompliance, provides this reportable situation. A preliminary report was offered by Stephanie Strahan (Chair, Rangos IACUC) on 2/16/18.

The IACUC Chair, in consultation with the IO, investigated the incident.

SoBran failed to provide veterinary rounds during the month of December 2017 at the Rangos facility in Baltimore, MD. Once the infraction was discovered, a back-up veterinarian was called in to perform animal health rounds. The two veterinarians responsible for care during the month of December are no longer with SoBran, nor working in any capacity associated with SoBran. Additionally, extra quality assurance checks have been implemented by the facility staff to ensure this does not occur again.

SoBran is committed to protecting the welfare of animals used in research and we are saddened by this occurrence. We appreciate Dr. Morse's timely guidance and the assistance provided by OLAW in this regard. Should you have any questions regarding this report or thoughts regarding our evaluation of this situation, please contact myself, Stephanie Strahan (former IACUC Chair), or Dr. Ann Schiavetta (current IACUC Chair).

Sincerely,

(b) (6)

Gregory Kelly, PhD  
Senior Vice President  
Institutional Official  
SoBran, Inc.

## Morse, Brent (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, August 16, 2018 12:07 PM  
**To:** Stephanie Strahan; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Ann Schiavetta; (b) (6)  
**Subject:** RE: OLAW Request for update on preliminary noncompliance report for A4614-K

Thank you for providing this report Ms. Strahan. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DAACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** Stephanie Strahan [mailto:SStrahan@sobran-inc.com]  
**Sent:** Wednesday, August 15, 2018 4:26 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Ann Schiavetta <ASchiavetta@sobran-inc.com>; (b) (6)@sobran-inc.com>  
**Subject:** FW: OLAW Request for update on preliminary noncompliance report for A4614-K

Good afternoon,

I received an out of office message for Neera Gopee. Please find attached a letter regarding an issue of noncompliance originally reported in February. Please let me know if you have any questions or need any additional information.

Thank you,  
Stephanie

**Stephanie Strahan, BS, CMAR, RLATG**

**Mobile:** (b) (6)



SoBran  
BioScience

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**From:** Stephanie Strahan  
**Sent:** Wednesday, August 15, 2018 4:21 PM  
**To:** 'Gopee, Neera (NIH/OD) [E]' <neera.gopee@nih.gov>  
**Cc:** Ann Schiavetta <aschiavetta@sobran-inc.com>; (b) (6)@sobran-inc.com>  
**Subject:** RE: OLAW Request for update on preliminary noncompliance report for A4614-K

Good afternoon,

Please find attached the letter regarding our issue of noncompliance reported in February. Please let me know if you have any questions or need any additional information.

Thank you,  
Stephanie

**Stephanie Strahan, BS, CMAR, RLATG**

Mobile: (b) (6)



SoBran  
BioScience

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**From:** Gopee, Neera (NIH/OD) [E] <[neera.gopee@nih.gov](mailto:neera.gopee@nih.gov)>

**Sent:** Friday, August 10, 2018 2:58 PM

**To:** Stephanie Strahan <[SStrahan@sobran-inc.com](mailto:SStrahan@sobran-inc.com)>

**Cc:** Ann Schiavetta <[ASchiavetta@sobran-inc.com](mailto:ASchiavetta@sobran-inc.com)>; (b) (6)@sobran-inc.com; (b) (6)

(b) (6)@sobran-inc.com>

**Subject:** RE: OLAW Request for update on preliminary noncompliance report for A4614-K

Thank you for your prompt response Stephanie, I look forward to receiving the final report next week.

Best Regards,  
Neera

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**From:** Stephanie Strahan [<mailto:SStrahan@sobran-inc.com>]

**Sent:** Friday, August 10, 2018 2:53 PM

**To:** Gopee, Neera (NIH/OD) [E] <[neera.gopee@nih.gov](mailto:neera.gopee@nih.gov)>

**Cc:** Ann Schiavetta <[ASchiavetta@sobran-inc.com](mailto:ASchiavetta@sobran-inc.com)>; (b) (6)@sobran-inc.com; (b) (6)

(b) (6)@sobran-inc.com>

**Subject:** RE: OLAW Request for update on preliminary noncompliance report for A4614-K

Hi Neera,  
I will send this to you next week.

Thanks,  
Stephanie

**Stephanie Strahan, BS, CMAR, RLATG**

Mobile: (b) (6)



SoBran  
BioScience

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**From:** Gopee, Neera (NIH/OD) [E] <[neera.gopee@nih.gov](mailto:neera.gopee@nih.gov)>

**Sent:** Friday, August 10, 2018 2:41 PM

**To:** Stephanie Strahan <[SStrahan@sobran-inc.com](mailto:SStrahan@sobran-inc.com)>

**Cc:** Ann Schiavetta <[ASchiavetta@sobran-inc.com](mailto:ASchiavetta@sobran-inc.com)>; (b) (6)@sobran-inc.com; (b) (6)

(b) (6)@sobran-inc.com>

**Subject:** RE: OLAW Request for update on preliminary noncompliance report for A4614-K

**Importance:** High

Dear Ms. Strahan,

As a follow-up to my email communication on July 26, 2018, OLAW still has no record of receipt of an interim or final report with reference to the preliminary noncompliance case reported on February 16, 2018, involving the failure of two veterinarians to visit the facility for one month at SoBran. This reminder is being sent requesting either the final or an interim report be submitted to OLAW Division of Compliance Oversight (NIH/OD) [olawdco@od.nih.gov](mailto:olawdco@od.nih.gov) no later than **August 27, 2018**.

Best Regards,  
Neera

Neera V. Gopee, DVM, PhD, DAACLAM, DABT  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** Gopee, Neera (NIH/OD) [E]  
**Sent:** Thursday, July 26, 2018 4:19 PM  
**To:** 'sstrahan@sobran-inc.com' <[sstrahan@sobran-inc.com](mailto:sstrahan@sobran-inc.com)>  
**Subject:** OLAW Request for update on preliminary noncompliance report for A4614-K

Dear Ms. Strahan,

I am writing with regards to the non-compliance case which was reported by via telephone on February 16, 2018 involving the failure of two veterinarians to visit the facility for one month at SoBran. To date we do not have a record of receiving further information regarding this preliminary report. OLAW requests that submission of a final or interim report to the OLAW Division of Compliance Oversight (NIH/OD) [olawdco@od.nih.gov](mailto:olawdco@od.nih.gov) at your earliest convenience.

If you have any questions or concerns regarding this matter, please do not hesitate to contact me.

Regards,  
Neera

Neera V. Gopee, DVM, PhD, DAACLAM, DABT  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**Gopee, Neera (NIH/OD) [E]**

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**From:** Gopee, Neera (NIH/OD) [E]  
**Sent:** Friday, August 10, 2018 2:58 PM  
**To:** 'Stephanie Strahan'  
**Cc:** Ann Schiavetta; (b) (6)  
**Subject:** RE: OLAW Request for update on preliminary noncompliance report for A4614-K

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Best Regards,  
Neera

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**From:** Stephanie Strahan [mailto:SStrahan@sobran-inc.com]  
**Sent:** Friday, August 10, 2018 2:53 PM  
**To:** Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>  
**Cc:** Ann Schiavetta <ASchiavetta@sobran-inc.com>; (b) (6)@sobran-inc.com>; (b) (6)@sobran-inc.com>  
**Subject:** RE: OLAW Request for update on preliminary noncompliance report for A4614-K

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Stephanie

**Stephanie Strahan, BS, CMAR, RLATG**  
**Mobile:** (b) (6)



**SoBran**  
**BioScience**

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**Subject:** RE: OLAW Request for update on preliminary noncompliance report for A4614-K  
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Neera V. Gopee, DVM, PhD, DACLAM, DABT  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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If you have any questions or concerns regarding this matter, please do not hesitate to contact me.

Regards,  
Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT  
Animal Welfare Program Specialist  
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Initial Report of Noncompliance

By: *aw*

Date: *2/16/18*

Time: *8:00*

Name of Person reporting: *Stephanie Strahan*

Telephone #: [REDACTED] (b) (6)

Fax #:

Email:

Name of Institution: *Sobran*

Assurance number: *A4614*

Did incident involve PHS funded activity?

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

*2 wets didn't come in for 1 month to do a visit*

Species involved:

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

*Replaced the wets*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_