



Animal Welfare Institute

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Via Email and USPS

Francis S. Collins, M.D., Ph.D., Director
National Institutes of Health
Building 1, Room 126
1 Center Drive
Bethesda, MD 20892
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Dear Director Collins:

On behalf of the Animal Welfare Institute (AWI), I am writing to urge you to take immediate action to close a loophole in the PHS Policy on Humane Care and Use of Laboratory Animals that [exempts “off-the-shelf” research antibodies produced in animals](#). I also respectfully request that you take additional action to address a serious systemic problem with animal care at Santa Cruz Biotechnology, Inc. (SCBT), a registered research facility and licensed dealer supplying both “off-the-shelf” and custom-made antibodies. Given the current loophole, it is critical that NIH hold grantee institutions accountable through their PHS Approved Statements of Assurance if they use custom-made antibodies supplied by SCBT.

Currently, the exemption in the PHS Policy allows inhumane treatment of animals used to supply blood products to NIH grantee institutions. SCBT has been cited repeatedly on USDA inspections for apparent egregious violations of the Animal Welfare Act (AWA) and a [complaint](#) has been filed by USDA’s Office of General Counsel. Despite these alleged violations, SCBT has continued to supply untold numbers of PHS-funded researchers with “off-the-shelf” research antibodies produced in animals, and the facility has apparently continued to flout the law.

During its compliance inspections conducted between July 2007 and December 2012, USDA cited SCBT on 13 separate occasions for failure to provide adequate veterinary care for goats used for blood collection, including citations for inadequate veterinary care at 9 separate inspections conducted in 2012 alone.

Goats were found in poor condition: some were lame, including those suffering from broken legs; others had respiratory conditions and nasal discharge; many were anemic; a number were extremely thin, with “protruding hips, ribs and spinal processes”; while others had skin conditions, including large areas of hair loss.

A goat with a broken leg had lost his cast and was in pain, yet the veterinarian stated that “she had not had time to attend to the goat in the last three days...she was unable to keep up with the workload...and there were insufficient support staff to provide for the medical care of the regulated animals at the facility.”
[April 19, 2012 inspection]

Despite the terrible condition of some of the goats, including those noted to be lame, or who had lost significant weight, or were anemic or had low hematocrit levels, SCBT persisted in drawing their blood. "Continuing to use these animals for antibody production with their history of medical conditions caused them unnecessary discomfort, distress, and pain....Animals with chronic and significant medical conditions are not suitable subjects for antibody production," states a May 5, 2010 USDA inspection.

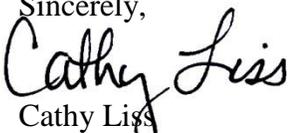
Among the most appalling findings by USDA is in its October 31, 2012 inspection which revealed that SCBT had willfully hidden from USDA the existence of a site housing 841 goats. "Several staff members as well as management at this facility failed to inform APHIS officials of the location of a site where regulated animals were housed and regulated activities (blood collection for antibody production) were taking place. The existence of the site was denied even when directly asked during APHIS inspections. By failing to disclose this information the registrant has interfered with APHIS officials and prevented them from carrying out their responsibility to enforce the Animal Welfare Act." The inspector found that "veterinary staff does not visit this herd," and reviewed SCBT's records regarding 12 goats identified by the inspector as having "significant health concerns"; the inspector stated that "none of these animals had received any treatment or veterinary observation." The inspection also cited the SCBT Institutional Animal Care and Use Committee (IACUC) for permitting unapproved changes in protocols that mandated that body weights and hematocrit levels be measured prior to blood collection in these goats.

Guidelines for antibody production in animals published by the [National Academy of Sciences' Institute for Laboratory Animal Research](#), [European Centre for the Validation of Alternative Methods](#), and the [Canadian Council on Animal Care](#), among others, state how carefully animals must be monitored and treated to avoid the very problems of suffering and distress that USDA repeatedly documented at SCBT; these guidelines include, for example, how important body weights are in determining the amount of blood to be taken.

The apparent violations of the AWA standards documented by USDA at this leading supplier highlights the need for an immediate change in the PHS Policy to close the exemption for companies selling off-the-shelf antibodies. AWI believes that antibody production in animals should clearly be included under the PHS Policy's definition of "an activity involving animals." Therefore, AWI urges that NIH remove the PHS Policy loophole for "off-the-shelf" research antibodies and immediately direct all PHS-funded researchers to only use vendors and/or suppliers of any product produced in animals that "comply, as applicable, with the Animal Welfare Act, and other federal statutes and regulations relating to animals" (quoted from PHS Policy, Section 2, Applicability). Since SCBT also supplies custom-made antibodies and this activity IS covered under the PHS Policy, AWI asks that NIH take action to address these gross AWA violations with any grant recipient who uses SCBT custom-made antibodies.

Thank you for your prompt consideration, and I look forward to hearing from you.

Sincerely,


Cathy Liss
President

cc: Patricia A. Brown, VMD, MS, Director, OLAW, brownp@od.nih.gov