March 7, 2011

Centers for Disease Control and Prevention  
Division of Global Migration and Quarantine  
Attn: NHP Rule Comments  
1600 Clifton Road, NE. (E03)  
Atlanta, GA 30333

Re:  Docket No. CDC-2011-0001 Requirements for Importers of Nonhuman Primates; Notice of Proposed Rulemaking

Dear Sir/Madam:

This letter is in response to the Centers for Disease Controls’ (CDC) solicitation of comments regarding the proposal to amend its regulations for the importation of live nonhuman primates (NHPs) by extending existing requirements for the importation of Macaca fascicularis (cynomolgus), Chlorocebus aethiops (African green), and Macaca mulatta (rhesus) monkeys to all NHPs.

The National Association for Biomedical Research (NABR) represents more than 300 public and private universities, medical and veterinary schools, teaching hospitals, voluntary health organizations, professional societies, pharmaceutical and biotech companies regarding sound public policy on the humane use of animals in biomedical research. NABR would like to acknowledge the efforts made by the CDC over the years in addressing the issues that have arisen related to the importation of NHPs for use in critical biomedical research and safety testing. Those efforts have not only prevented the introduction, transmission, and spread of communicable diseases from foreign countries into the United States, they have served to almost eliminate the mortality of those animals that are imported.

While NABR supports the intent of the proposed changes to extend the current regulations to all NHPs; to reduce the administrative burden on importers currently covered under these regulations by extending the re-registration period from six months to 2 years; and to permit the laboratory-to-laboratory transfers of NHPs on established research protocols, the following comments address specific language that we believe should be clarified to further reduce the administrative burden.

71.53 Requirements for importers of nonhuman primates.

(c) Acronyms, Initialisms, and Definitions – The definition of zoonotic disease is not consistent with the definition in the background information nor is it consistent with
the definition as found in a medical dictionary. It should be amended to read, “Zoonotic Disease means any infectious agent or communicable disease that is able to be transmitted from animals, both wild and domestic, to humans.”

(i) Worker Protection Plan and Personal Protective Equipment - The requirement in Section (3) that any instance of a worker being exposed to a zoonotic illness must be reported immediately by telephone should be changed to be consistent with other similar reporting requirements. This section should read “An importer must immediately contact CDC by telephone, SMS text, or e-mail, as specified in the importer’s standard operating procedures, to report any instance of a worker exposed to a zoonotic illness and must include instructions for contacting CDC in its worker protection plan.” The same language should be used in Section (9) to read, “The importer must promptly notify CDC by telephone, SMS text, or e-mail as specified in the importer’s standard operating procedures if such illness occurs.”

(k) Ground Transport Vehicles - Section (5) should be revised to read, “After transport of the NHP shipment from the port of entry to the quarantine facility, the importer must notify CDC in writing, SMS text, or e-mail as specified in the importer’s standard operating procedures within 48 hours of the time the shipment arrived at the quarantine facility.”

(l) Quarantine Facilities – In section (3)(viii)(B) the importer is required to collect serum samples from animals displaying suggestive signs of filovirus infection that survive the 31 day quarantine period for testing for antibodies for filovirus. In section (6)(viii) the importer is required to submit liver tissue for filovirus antigen testing if an animal dies or is euthanized during quarantine. The rationale for this difference is unclear to us, and we suggest the section (6)(viii) be changed to read, “In the event that an Old World NHP dies or is euthanized during quarantine while showing signs of filovirus infection (e.g. diarrhea with melena or frank blood, bleeding from external orifices or petechiae, or suffusive hemorrhage) liver tissue must be submitted to a laboratory for testing for filovirus antigen using the antigen-capture ELISA method.”

(l) Quarantine Facilities – There appears to be an inconsistency in the requirements for Section (6)(ii) and (iv). Section (6)(ii) requires that necropsies be performed under “biosafety level 3 containment”, while (6)(e) requires they be “performed under biosafety level 3 or biosafety level…”

(n) Recordkeeping and Reporting Requirements for Importing NHPs – Section (2) should be revised to read, “At least seven days before importing a shipment of NHPs, an importer must notify CDC in writing or by e-mail of the impending shipment and provide the following information:”

It is unclear why the language for medical records and health certificates for, Zoo-to-Zoo and Laboratory-to-Laboratory Transfers are not consistent. We would recommend that the language be changed to read:
“(i) A copy of each NHP's veterinary medical records, including regular testing for tuberculosis from the previous lab (or zoo) for CDC's approval. The medical record should include a positive identification of the NHP, such as a tattoo, microchip, or photograph.

(ii) A copy of a current health certificate, including documentation of a negative tuberculosis test, signed by a licensed qualified veterinarian within 14 days of the transfer documenting that the NHP appears healthy and free from communicable diseases, and…”

NABR appreciates the opportunity to comment on the proposed changes in the current regulations pertaining to importation of nonhuman primates under the Public Health Service Act.

Sincerely,

Frankie L. Trull
President