Dear Dr.,

This Warning Letter informs you of objectionable conditions observed during a Food and Drug Administration (FDA) inspection conducted between June 17, 2016, and July 11, 2016. FDA investigators met with you during the inspection to review your conduct as a sponsor and clinical investigator of the following clinical studies:

(b)(4)

The FDA conducted this inspection under the Bioresearch Monitoring Program that includes inspections designed to review the conduct of research involving investigational products. At the end of the inspection a Form FDA 483, Inspectional Observations, was issued and discussed with you.

Based on our review of the establishment inspection report, the documents submitted with that report, and your July 22, 2016, response to the Form FDA 483 ("response letter"), we have determined that you violated regulations governing the proper conduct of clinical studies involving investigational new drugs, as published in Title 21, Code of Federal Regulations (CFR) Part 312 (available at http://www.gpoaccess.gov/cfr/index.html). The applicable provisions of the CFR are cited for each violation listed below.
SPONSOR VIOLATIONS:

1. You failed to fulfill the general responsibilities of sponsors and to ensure that investigations are conducted in accordance with the general investigational plan and protocols contained in the IND. [21 CFR § 312.50].

A sponsor is responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly, ensuring proper monitoring of the investigation(s), ensuring that the investigation(s) are conducted in accordance with the general investigational plan and protocols contained in the Investigational New Drug Application (IND), maintaining an effective IND with respect to the investigations, and ensuring that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug.

You failed to ensure that the investigations were conducted in accordance with the general investigational plan and protocols contained in your INDs. Specifically:

A. Section 13 of the (b)(4) protocol required you to report all life-threatening or lethal (Grade 4 and 5) (except grade 4 (b)(4)) reactions within "72 hours of a working day" to the FDA and (b)(4) after the report was made to you. It further required you to report Grade 3 reactions to FDA on annual reports. You failed to identify and report Grade 3 reactions to FDA in an annual report as required by the protocol for site 101.

i. Source records show that Subject (b)(6) experienced adverse events (AEs) including a chest infection, vertigo worsening, narcolepsy worsening, stuttering worsening, hyperglycemia, elevated transaminases, diarrhea, neutropenic fever, hypotension, and rhinitis during the period from November 2014 until April 2016. You failed to evaluate these AEs and did not report any of these events to FDA until July 7, 2016, during the inspection, when you reported the following Grade 3 toxicities: febrile neutropenia, hypophosphatemia, hyperglycemia, and elevated transaminase.

ii. Source records show that Subject (b)(6) experienced AEs including hypertension, fatigue, dyspepsia, transaminase elevation, sore throat, sinus tachycardia, liver function test elevation, CMV positive, shingles, unstable patella, and a dislocated finger during the period from June 2013 to May 2015. You failed to evaluate these AEs and did not report any of these events to FDA until July 7, 2016, during the inspection, when you identified hypertension as a Grade 3 toxicity.

Your response letter explains that you provided all Grade 3 toxicities from subjects at the [ ] site (site 101) in an Annual Report sent to FDA on July 12, 2016. Your response letter elsewhere states that there were no grade 4 toxicities at the [ ] site.

We acknowledge your submission of Grade 3 toxicities to FDA on July 12, 2016. However, your response is not acceptable because you did not indicate that you have put a corrective action plan in place to prevent similar violations in the future.

B. You failed to ensure that investigators at sites 102-105 assessed and reported toxicity as required by the (b)(4) protocol. Section 12 of the (b)(4) protocol required daily assessment of toxicity by an investigator, and use of the Common Toxicity Criteria Scale to grade all non-hematologic toxicities. Section 13 of the (b)(4) protocol required clinical investigators to report all life-threatening and lethal (Grade 4 and 5) (except grade 4 (b)(4)) reactions by telephone to you immediately, and to report all Grade 3 reactions in writing to you within 10 business days.
Our inspection found no evidence that clinical investigators at sites 102-105 conducted the toxicity assessments required by the (b)(4) protocol, and we therefore conclude that you did not ensure that these toxicity assessments were performed. During the inspection you requested that your staff review the available Case Report Forms (CRFs) and some source records submitted to you from sites 102-105 for AEs. This review was not comprehensive due to the lack of a CRF developed specifically to capture all AEs during the time of the inpatient transplant. You reported the findings of your limited review to FDA in an Annual Report submitted on July, 7, 2016.

We acknowledge that the findings noted here in Item 1.B were not included on the Form FDA 483 you received, and that therefore, your written response does not address these findings. However, we believe that certain of your responses to other, related items are applicable here.

In particular, your response letter explains that sites 102-105 did not report any treatment related Grade 3 or 4 toxicities during transplant. In addition you planned to conduct site visits at the three enrolling sites in October 2016 and intended to review their transplant records to determine if any Grade 3 or 4 toxicities have occurred. You planned to provide a report of the visits to FDA in November 2016. You developed forms to be completed and signed off during the site visits including: investigator and study nurse training forms, CRF outcome form, CRF adverse event form, site inspection form, site monitoring activity log, communication log, and patient enrollment form.

Your response is acceptable. Please submit the documentation from your visits to sites 103, 104, and 105.

C. You failed to ensure that two of four deaths in the (b)(4) protocol were reported to FDA and to the IRB within 72 hours as required by section 9.1 of the (b)(4) protocol. The (b)(4) protocol required the clinical investigator to report by phone "all life-threatening or lethal (Grade 4 and 5) (except grade 4 (b)(4) which is anticipated) reactions. This information is to be immediately reported to Dr. Richard Burt who will report it within 72 hours of a working day to the IRB and FDA." Chapter 9 of the (b)(4) protocol generally noted that "the toxicity grading for adverse events is according to NCI common criteria for adverse events (CTCAE) version 2.0[.]"

i. Subject (b)(6) underwent a Human Stem Cell Transplant (HSCT) on (b)(6). The subject died on (b)(6), from renal stone complications. Your site was aware of the subject’s death on February 1, 2010. You did not report the subject’s death to the FDA until August 2, 2011.

ii. Subject (b)(6) underwent an HSCT on (b)(6). The subject died on (b)(6), from pneumonia. Your site was aware of the subject’s death on April 2, 2014. You reported the subject’s death to FDA on March 24, 2015.

Your response letter acknowledges that the deaths of these two subjects were not reported to FDA within 72 hours after learning of the death. Your response letter explains that you “instructed all staff in the division that I must notify FDA immediately (within 72 hours) of us becoming aware of any death for any reason.”

Your response letter further explains that you notified the IRB of the deaths of these subjects. Your corrective actions to ensure reporting of deaths to FDA and IRB include: reconfiguring your team, holding an IRB training course for all staff, informing staff that you must be notified immediately of any subject death, and assigning a study nurse who has daily contact with the clinical investigator to coordinate IRB and FDA reporting.
We are unable to undertake an informed evaluation of your response because you did not provide documentation further explaining your corrective action plan, for example, a Standard Operating Procedure (SOP) that shows your staff is to notify you immediately upon becoming aware of any death and that you will report deaths to FDA and the IRB within 72 hours.

D. You failed to report all Grade 3 and Grade 4 reactions to FDA in Annual Reports as required by section 9.2 of the (b)(4) protocol. Chapter 9 of the (b)(4) protocol generally noted that "the toxicity grading for adverse events is according to NCI common criteria for adverse events (CTCAE) version 2.0 [\textsuperscript{1}] ." During the inspection, you compiled a list of all Grade 3 and 4 reactions for the (b)(4) study. You reported the findings of your review during the inspection to FDA in an Annual Report submitted on July 7, 2016. Examples of Grade 3 and Grade 4 toxicities submitted to FDA on July 7, 2016, but not previously evaluated and reported include:

i. Subject (b)(6) "Grade 3: neuropathy (motor)-inability to move L arm and leg (recovered two weeks later), hypokalemia, hypophosphatemia, infection (+ C.diff);" "Grade 4: intracranial hemorrhage (requiring craniotomy)"

ii. Subject # (b)(6): "Grade 3: Neutopenic Infection + Cdiff toxin, hypertension. Grade 4: none."

iii. Subject # (b)(6): Grade 3: (fever) non-neutopenic >40.0C. Grade 4: none"

Your response letter states that you included all Common Toxicity Criteria (CTC) Grade 3 and 4 toxicities in an Annual Report submitted to FDA on July 7, 2016. Your response is not acceptable because you did not indicate that you have put a corrective action plan in place to prevent similar violations in the future.

E. You failed to ensure that interim analyses were conducted as required by the (b)(4) protocols. According to Section 15.2 of the (b)(4) protocol, interim analyses using outcomes such as time to treatment failure and survival were to be conducted after 25%, 50%, and 75% of patients were entered into the study to assess whether the study should continue or be closed: (b)(4) and approved by the IRB, DSMB, and the US FDA. The protocol further provided that the "triggering of stopping rules or any hold on the protocol will prompt cessation of new enrollment, notification of the IRB and FDA and performance of a comprehensive safety review by the DSMB and external advisor. . . . the data will be analyzed once follow-up clinical data are available on 25, 50 and 75 of the targeted number of patients. Data will be reviewed by the External Advisor, (b)(4). . . and provided to the IRB and FDA if any significant differences are detected."

Your response letter explains that you "understand the confusion around this point" and "wish to clarify my intent and understanding." Your response further explains "The interim analysis was not to determine efficacy but rather only as a stopping rule if the treatment group was accumulating more (b) (4) compared to control. If more people were accumulating (b)(4) in the treatment group compared to control then we would have done a statistical analysis to determine significance in order to determine if we needed to stop the study."

Your response is not acceptable because you did not indicate either that you will submit a protocol amendment to edit the protocol to more accurately reflect your intent or that you have put a corrective action plan in place to prevent similar violations in the future.

2. You failed to submit a protocol amendment to FDA when there was a significant change in protocol design. [21 CFR § 312.30(b)(1)(ii) and 312.30(b)(2)(i)(a).] Further, you failed to submit a
protocol amendment to FDA when new investigators were added to carry out a previously submitted protocol within 30 days of the investigators being added. [21 CFR § 312.30(c.)]

A. You failed to submit a protocol amendment within 30 days of adding the following five clinical investigators at four investigational sites to the (b)(4) Protocol:

- Dr. ... (Canada Site 102) who enrolled 2 subjects between 2009 and 2010.
- Dr. ... and Dr. C.O. (Brazil Site 103) who enrolled 3 subjects between 2009 and 2014.
- Dr. ... (Sweden Site 104) who enrolled 14 subjects between 2011 and 2016.
- Dr. ... (United Kingdom Site 105) who enrolled 11 subjects between 2014 and 2016.

During the inspection, we found that you prepared new protocol versions when you added new investigators; however you failed to submit these protocol amendments to FDA.

<table>
<thead>
<tr>
<th>Version Number</th>
<th>Version Date</th>
<th>Investigator Addition</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>6/25/07</td>
<td>Added clinical investigators from two new sites, Brazil and Canada</td>
</tr>
<tr>
<td>15</td>
<td>12/11/13</td>
<td>Added clinical investigator from two new sites, Sweden and the United Kingdom</td>
</tr>
<tr>
<td>17</td>
<td>9/25/14</td>
<td>New clinical investigator in Brazil</td>
</tr>
</tbody>
</table>

Your response letter states that you submitted a Form FDA 1572 and curriculum vitae for the investigators at the current enrolling sites to FDA on July 12, 2016. Your response is not acceptable because you did not indicate that you have put a corrective action plan in place to prevent similar violations in the future.

B. You failed to report significant changes in the design of the (b)(4) protocol to FDA. The following table shows nine protocol versions containing significant changes in protocol design that were not submitted to FDA. You submitted Version 19 to FDA on July 14, 2016, after the inspection ended.

<table>
<thead>
<tr>
<th>Version #</th>
<th>Version Date</th>
<th>Investigators Added</th>
<th>Inclusion/Exclusion Criteria</th>
<th>Study Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>4/18/07</td>
<td>None</td>
<td>Add Exclusion for (b)(4)</td>
<td>(b)(4)</td>
</tr>
<tr>
<td>7</td>
<td>6/25/07</td>
<td>Added clinical investigators from two new sites: Brazil and Canada</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>9</td>
<td>1/7/08</td>
<td>None</td>
<td>None</td>
<td>Add Appendix IX, (b)(4) Protocol</td>
</tr>
<tr>
<td>13</td>
<td>1/4/11</td>
<td>None</td>
<td>None</td>
<td>(b)(4)</td>
</tr>
<tr>
<td>14</td>
<td>7/29/13</td>
<td>None</td>
<td>None</td>
<td>(b)(4)</td>
</tr>
<tr>
<td>15</td>
<td>12/11/13</td>
<td>Added clinical investigators from two new sites: Sweden and the United Kingdom</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>17</td>
<td>9/25/14</td>
<td>New clinical investigator in Brazil</td>
<td>Remove Exclusion for (b)(4)</td>
<td>None</td>
</tr>
<tr>
<td>18</td>
<td>12/17/14</td>
<td>None</td>
<td>Add Exclusion for (b)(4)</td>
<td>None</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Version #</th>
<th>Version Date</th>
<th>Investigators Added</th>
<th>Inclusion/Exclusion Criteria</th>
<th>Study Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>19</td>
<td>12/22/15</td>
<td>None</td>
<td>None</td>
<td>(b)(4)</td>
</tr>
</tbody>
</table>

Your response letter explains that protocol changes were made to include new FDA approved drugs for the control arm. You state that the changes were IRB approved; however, they were not sent to FDA in a timely manner. Although you indicated that you have sent updated versions of the protocol to FDA, your response is not acceptable because you did not indicate that you have put a corrective action plan in place to prevent similar violations in the future. In particular, your response letter does not explain how you plan to ensure that significant changes in protocol design, including addition of new clinical investigators, will be submitted to FDA in the future.

We acknowledge that this finding for protocol versions 6 (Exclusion Criterion), 7, 9, 13 (add (b)(4)), 14, 15, 17, and 18 were not included on the Form FDA 483 you received, and that therefore, your written response does not address this finding for these protocol versions.

3. You failed to select investigators qualified by training and experience as appropriate experts to investigate the drug. [21 CFR § 312.53(a)].

As described below at Item 4, you did not evaluate the qualifications of investigators participating in the (b)(4) study by reviewing their curricula vitae (CV) or medical licensure prior to allowing them to serve as clinical investigators in the (b)(4) study. During the inspection, you stated that you had no knowledge of the training and experience of the investigator at Site 102 in Canada. You explained that you knew the investigators at Sites 103, 104, and 105 by professional reputation.

In an electronic communication to site 102 on March 6, 2011, you further acknowledged that there was no qualified clinical investigator at Site 102: "There is no transplant physician at your site with the authority or dedication to see and evaluate and be responsible for the daily inpatient care, coordination, and unique complications of HSCT for (b)(4)." You arrived at this conclusion and suspended Site 102 from further enrolling study subjects only after Site 102 enrolled and performed HSCTs on two subjects who did not meet protocol eligibility criteria. Subject (b)(6) was enrolled on June 3, 2009, and transplanted on (b)(6), and Subject (b)(6) was transplanted on (b)(6). These two subjects did not meet the eligibility criteria of the protocol in that they had been diagnosed with (b)(4), which was a contraindication listed in the protocol. They were included in the study, and inappropriately received HSCTs, because of the oversight of an unqualified clinical investigator whom you had selected.

We acknowledge that this finding was not included on the Form FDA 483 you received, and that therefore, your written response does not address this finding. Please describe how you will select qualified investigators in the future; for example, in the event an additional clinical investigator is required at site 103, 104, or 105.

4. You failed to obtain certain required information from investigators prior to permitting their participation in the clinical investigation, including a signed investigator statement, curriculum vitae, and financial disclosure information. [21 CFR § 312.53(c)].

You failed to obtain a signed Statement of Investigator FDA Form 1572, curriculum vitae (CV) or other statement of qualifications showing the education, training, and experience that qualifies the investigator as an expert in the clinical investigation of the investigational drug, and sufficient accurate
financial disclosure information to allow you to submit complete and accurate certification or disclosure statements as required under 21 CFR Part 54, from five clinical investigators at Sites 102 (Dr. J.S.), 103 (Dr. J.V. and Dr. C.O.), 104 (Dr. J.B.), and 105 (Dr. B.S.) prior to their participation in the (b)(4) study.

On July 30, 2016, during the FDA inspection, your staff requested a Form FDA 1572 and CV from the clinical investigators currently active in the (b)(4) study. FDA Form 1572s and CVs were received during the FDA inspection for the following clinical investigators with the following associated dates: Site 103 investigator C.O. dated June 30, 2016; Site 104 investigator J.B. dated June 30, 2016; and Site 105 investigator B.S. dated July 1, 2016.

Your response letter explains that you submitted the CVs and signed Form FDA 1572s noted above to FDA on August 16, 2016, and that you have asked each site clinical investigator to complete and sign FDA 3454 and 3455 financial disclosure forms. You explain that Site 102 will not cooperate to provide information for the clinical investigator at that site because the site was closed in 2011, and that clinical investigator J.V. of Site 103 has died. Your response is not acceptable because you did not indicate that you have put a corrective action plan in place to prevent similar violations in the future. Please describe your corrective action to obtain a Form FDA 1572, CV or other statement of qualifications, and the requisite financial disclosure information in advance from any future investigators; for example, in the event an additional clinical investigator is needed at site 103, 104, or 105.

5. You failed to give each participating investigator an investigator brochure containing the information described in 21 CFR § 312.23(a)(5). [21 CFR § 312.55(a)].

You failed to provide clinical investigators at sites 102, 103, 104, and 105 of the (b)(4) study with investigator brochures before the investigation began. As described in the FDA Guidance for Industry incorporated from the International Conference on Harmonization (ICH) entitled E6 Good Clinical Practice: Consolidated Guidance, the Investigator’s Brochure is a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration, and safety monitoring procedures.

You submitted the “(b)(4) Protocol Brochure” to FDA on August 16, 2016. We do not have any evidence that you supplied this brochure to clinical investigators at sites 102, 103, 104, or 105 before the investigation began.

We acknowledge that this finding was not included on the Form FDA 483 you received, and that therefore, your written response does not address this finding. Please describe any corrective actions you have taken or will take to ensure that you provide an investigator brochure to each participating investigator prior to initiating an investigation in the future.

6. You failed to monitor the progress of clinical investigations being conducted under your IND. [21 CFR §§ 312.50 and 312.56(a)].

As the sponsor of the (b)(4) study you are responsible for ensuring that this study is adequately monitored for compliance with regulatory requirements, thereby ensuring the data quality, and that the rights, safety, and welfare of study subjects are adequately protected. The inspection showed that you failed to monitor the progress of the (b)(4) protocol at the following three sites:

• Site 103 in Sao Paulo, Brazil, enrolled three subjects between 2009 and 2014.
• Site 104 in Uppsala, Sweden, enrolled 14 subjects between 2011 and 2016.
• Site 105 in Sheffield, United Kingdom, enrolled 11 subjects between 2014 and 2016.

You did not conduct site visits, review the study sites, or use other monitoring techniques to oversee the conduct of, and reporting of data from, these clinical investigation sites, including appropriate Clinical Investigator supervision of study site staff. You explained to the FDA investigators that your primary communication with these sites was through email and attendance at Annual Meetings held in

During the inspection, you provided agendas for these Annual Meetings; however, the agendas are not specific to the (b)(4) study and do not include details regarding the items discussed. We are unable to determine that adequate monitoring occurred at these annual meetings because we have no evidence to show attendance at the Annual Meetings, no evidence of training conducted, and no evidence to show specific information exchanged during the Annual Meetings regarding AEs, protocol amendments, updates, or compliance issues.

Your response letter states that you provided the “(b)(4) Monitoring Plan” to FDA on August 16, 2016. According to the “(b)(4) Monitoring Plan” you intend to conduct on-site monitoring every two years. Your response letter also states that you plan to visit sites 103, 104, and 105 in October 2016 and intend to provide a report to the FDA in November 2016. You developed forms to be completed and signed off during the site visits including: investigator and study nurse training forms, CRF outcome form, CRF adverse event form, site inspection form, site monitoring activity log, communication log and patient enrollment form. Please submit the documentation from your visits to sites 103, 104, and 105.

7. You failed to make adequate annual reports to FDA as required by § 312.33. [21 CFR § 312.56(c)].

A. As described at items 1.B. and 6, you did not report to FDA that your investigational plan for the (b) (4) clinical trial had been altered to include sites 102 (Canada), 103 (Brazil), 104 (Sweden), and 105 (United Kingdom). You also did not include any information regarding these sites in your Annual Reports to FDA as required by 21 CFR § 312.33, including the number of subjects entered into the study or a list of subject who died during participation in the study.

We acknowledge that this finding was not included on the Form FDA 483 you received, and that therefore, your written response does not address this finding. We note that your response letter states that you reported the closure of site 102 to FDA in 2011 and submitted an Annual Report to FDA on July 12, 2016, that provided information on all sites “including the number of patients enrolled, safety and (b)(4) outcome.” Please explain how you intend to comply with the Annual Reporting requirements outlined in 21 CFR § 312.33 in the future.

B. You failed to report two deaths in the (b)(4) study to the FDA in an Annual Report as required by 21 CFR § 312.33, as described at item 1.C above.

We acknowledge that this finding was not included on the Form FDA 483 you received, and that therefore, your written response does not address this finding. We note that your response letter acknowledges that the deaths of these two subjects were not reported to FDA within 72 hours after learning of the death, as required by the (b)(4) protocol. Your letter explains that you instructed your staff that you must notify FDA immediately (within 72 hours) of becoming aware of any death for any reason and your staff will also complete an IRB course. Please explain how you will comply with the requirements of 21 CFR § 312.33 in future.
CLINICAL INVESTIGATOR VIOLATION:

8. You failed to ensure that the investigation was conducted according to the signed investigator statement, the investigational plan, and the applicable regulations, and to protect the rights, safety, and welfare of subjects under your care. [21 CFR § 312.60].

As a clinical investigator, you are required to ensure that your clinical studies are conducted in accordance with the investigational plan.

A. As a clinical investigator for the (b)(4) protocol at site 101, you failed to identify, evaluate, and report toxicities as required by Section 12.0 of the protocol, which states that "Daily assessment will be made with regards to toxicity by one of the protocol investigators. Common Toxicity Criteria Scale will be used to grade all non-hematologic toxicities."

You failed to assess toxicity on a daily basis as required by the protocol as evidenced by the fact that you identified and evaluated adverse events for toxicity during the FDA inspection. Item 1.A. above provides examples of your failure to identify and evaluate adverse events on a daily basis.

B. As a clinical investigator for the (b)(4) protocol you failed to identify, evaluate, and report toxicities in accordance with section 8 of the protocol, which states that "Assessment will be made with regards to toxicity by one of the protocol investigators. Common Toxicity Criteria Scale (see appendix) will be used to grade all non-hematologic toxicities."

You failed to assess toxicity on a daily basis as required by the protocol as evidenced by the fact that you compiled a list of Grade 3 and 4 toxicities during the FDA inspection. Item 1.D. above provides examples of Grade 3 and Grade 4 toxicities that you failed to identify as required by the protocol.

We acknowledge that the findings noted here at Items 8.A. and 8.B. were not included on the Form FDA 483 you received, and that therefore, your written response does not address this finding. Please explain how you intend to ensure that your clinical studies are conducted in accordance with the investigational plan in the future. This letter is not intended to be an all-inclusive list of deficiencies with your clinical studies of investigational new drugs. It is your responsibility to ensure adherence to each requirement of the law and relevant FDA regulations.

Within fifteen (15) business days of receipt of this letter, please provide written documentation of the additional actions you have taken or will take to correct these violations and to prevent the recurrence of similar violations in current and future studies for which you are the sponsor and/or clinical investigator. Failure to respond to this letter and to take appropriate corrective action could result in FDA taking regulatory action without further notice to you. If you do not believe you are in violation of FDA regulations, include your reasoning and any supporting information for our consideration.

Your reply should be sent to me at the following address: U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., WO71 - G112, Silver Spring, MD 20993-0002. If you have any questions regarding this letter, please contact the Division of Inspections and Surveillance, CBER at 240-402-8928.

We also request that you send a copy of your response to the FDA District Office listed below.

Sincerely,
/S/

Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

cc:

Dist

Research Subjects

32

Close Out Letter

More in 2016

https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm548176.htm