DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Biologics Evaluation and Resea
1401 Rockville Pike
Rockville MD 20852-1448

Notice of Initiation of Disqualification Proceeding
And Opportunity to Explain

By Certified Mail – Return Receipt Requested
And By Facsimile Transmission

APR 22 2004

Eugenia Marcus, M.D.
Pediatric Health Care at Newton-Wellesley, P.C.
2000 Washington Street, Suite 201
Newton, Massachusetts 02462

Dear Dr. Marcus:

The Food and Drug Administration (FDA, or the Agency) has investigated allegations that you failed to fulfill the responsibilities of a clinical investigator for studies involving infant patients utilizing unlicensed biological investigational new drugs, a [redacted] vaccine and an [redacted] vaccine, in violation of FDA regulations governing investigational new drugs. Between April 1 and April 18, 2003, Monique C. Lo and Andrew M. Barlow, investigators from the FDA New England District Office, met with you and clinical study personnel and inspected the records relating to the use of the investigational [redacted] vaccines. This inspection was conducted as part of the FDA's Bioresearch Monitoring Program that includes inspections designed to review the conduct of clinical research involving investigational products. The inspection focused on the studies titled [redacted] and [redacted], hereafter referred to as [redacted]

The Form FDA 483 "Inspectional Observations" was presented and discussed with you and other study personnel at the end of the inspection. You responded in a letter to FDA dated June 2, 2003 (your response letter). We reviewed your response letter and have accepted your explanation for some items listed on the Form FDA 483. Our comments on other noted violations are set forth below. This letter includes violations that did not appear on the Form FDA 483, and this letter provides the opportunity for you to reply.

Based on the results of the inspection and other information available to the Agency, we believe that you repeatedly or deliberately violated regulations governing the proper conduct of clinical studies involving investigational new drugs as set forth under Title 21, Code of Federal Regulations (CFR), Parts 312 and 50, and repeatedly submitted false information to the sponsor in required reports. The regulations are available at http://www.access.gpo.gov/nara/cfr/index.html.

This letter provides you with written notice of the matters under complaint and initiates an administrative proceeding, described below, to determine whether you should remain entitled to receive investigational new drugs, as set forth in 21 CFR § 312.70.

A listing of the violations follows. The applicable provisions of the CFR are cited for each violation.

1. **You failed to fulfill the general responsibilities of an investigator. [21 CFR § 312.60 and Part 50].**

   An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and, for the control of drugs under investigation. Our investigation revealed that you did not fulfill your obligations as the clinical investigator in the use of investigational new drugs because you failed to adequately supervise the clinical investigations and failed to adequately protect the rights, safety, and welfare of subjects.

   On September 6, 2001, and on several occasions thereafter, you signed a Form FDA 1572, Statement of Investigator, which clearly enumerates the commitments you agreed to as clinical investigator. You failed to fulfill the commitments in this agreement in that you initiated clinical studies utilizing investigational new drugs in pediatric subjects without personally conducting or supervising the clinical investigation. As the clinical investigator, you may delegate authority to perform certain research procedures to other qualified personnel. However, such delegation requires adequate supervision of those to whom you delegate authority. As the investigator of record, you were responsible for overseeing and reviewing the work of the subinvestigators and study staff to make certain that they were following the investigational study plan.

   In your response letter, you attribute the observations listed on the Form FDA 483 to one individual, [redacted] your former study coordinator. You acknowledge that you "now know that...the ultimate responsibility for compliance with Good Clinical Practices (GCP) and FDA requirements lies with me as the PI." Although you attribute many of the allegations in this letter to a single individual, several allegations involve other study staff. Taken as a whole, these

allegations illustrate that you failed to effectively supervise the individuals under your direction and failed to fulfill the responsibilities of an investigator.

A. You failed to obtain informed consent in accordance with 21 CFR Part 50, as described in item 4., below. You stated in your letter that you were "not sufficiently familiar with all of the details for obtaining informed consent..." yet you signed several Forms FDA 1572 agreeing to "ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 ...are met." You placed the health and safety of infant study subjects at risk when you failed to effectively train, manage, and supervise study staff to ensure that the parents/guardians of potential subjects enrolling in the studies were fully informed of the risks and potential benefits associated with the studies and that they understood their rights as study participants.

B. You failed to protect the health and safety of subjects in your care by failing to perform required follow-up safety contacts. While under your supervision, [redacted] failed to contact the parents/guardians of study subjects to perform the safety checks required by the protocol, yet she recorded in the case report forms that she had made the contacts and that the infant subjects had not experienced problems that could be related to the study. Protocol [redacted] required these safety contacts to ensure that participating subjects did not develop [redacted], a potentially life-threatening [redacted] complication. Protocol [redacted] required these contacts to collect information about adverse reactions, concomitant medication use, and health care provider visits after vaccination. The failure to perform the safety evaluations for study [redacted] is especially egregious because of the known association of this vaccine with rare instances of [redacted] After stating the [redacted] risk, the informed consent document assured the parents/guardians of potential subjects that "Your child may get a benefit from the increased medical attention, since the study doctor and his/her staff will be checking your child closely for safety reasons." These safety checks were simply not performed for the 11-month duration of the study at your site.

In your response letter, you state that you did not "fully appreciate" your "responsibilities as the Principle [sic] Investigator (PI) and relied too heavily" on your former clinical research coordinator. You also admit that you did not provide "sufficient oversight" for this employee.

C. You failed to properly train and supervise subinvestigators and other staff involved in studies [redacted] and [redacted] By signing the Form FDA 1572 you agreed "to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations..." The following examples are provided for illustration:

Individuals not participating in the investigation administered study drug to subjects. Study personnel and their designated responsibilities are listed on the "Study Site Personnel Signatures & Responsibilities Form" while their signatures are recorded on the "Site Signature Log." Personnel not included as study participants administered study drug to two subjects as described below.

i. [redacted] administered study drug to subject [redacted] on [redacted] In a Note-To-File dated 1/29/03, you explain that [redacted] instructed [redacted] to randomize subjects and administer study drug in her absence although he was not instructed to obtain information pertaining to [redacted] or serious adverse experiences, and was not instructed to collect pediatric supplementary information. According to your response letter, you first became aware that he had administered study drug on 11/13/02. He was not included in the "Study Site Personnel & Responsibilities Form" until 11/13/02 and the "Site Signature Log," a listing of study participant's signatures, until 11/15/02.

ii. [redacted] administered study drug to subject [redacted] on [redacted] She was not added to the "Site Signature Log" until 4/18/03, when you learned through the FDA investigators that she had administered study drug.

In your response letter, you agreed with these observations for subjects [redacted] and [redacted]

2. You failed to ensure that the investigation is conducted according to the investigational plan. [21 CFR § 312.60].

A. You failed to complete post-vaccination follow-up safety contacts as required by the protocol. Protocol [redacted] required that the clinical investigator contact the parent/guardian of the infant subjects on days 7, 14, and 42 following each dose of study vaccine/placebo to determine whether adverse reactions had occurred. Protocol [redacted] required that the clinical investigator contact the parent/guardian of the infant subjects to conduct follow-up safety contacts after the administration of each dose of study vaccine/placebo based on randomization groups as follows: safety contacts for Groups 1 and 2 on days 3, 14, 28, and 42 post-visit 1; days 3 and 10 for Groups 1 and 2 post-visit 2 and 3, and Group 3 post-visit 1 and 2. Your site did not perform these required follow-up safety contacts for the subjects as listed in table 3.A. below.

In your response letter, you stated that you agree with the observation and "this problem was unknown to me, and was an aberration by an employee, who I acknowledge was not provided sufficient oversight."

We note that subjects [redacted] and [redacted] were not specifically included on the Form FDA 483.

B. Although you enrolled six subjects in study [redacted] none of them successfully completed the study. Two subjects were discontinued from the study because they did not receive the designated dose of study drug in proper sequence according to visit number and study group randomization. Subject [redacted] received the Visit 3 dose of study drug at Visit 1 on [redacted] and the Visit 1 dose of study drug at Visit 3 on [redacted] On [redacted] Subject [redacted] was randomized to study Group 1/2 and was incorrectly administered study drug designated for a Group 3 participant. These errors occurred despite the fact that each package of study drug was clearly labeled and color-coded as to visit number and randomization group.

Item 2.B. was not included on the Form FDA 483.

C. You failed to follow the protocol by enrolling subjects who did not satisfy the eligibility criteria and for whom no waiver was obtained from the sponsor.

i. You enrolled subject [redacted] in protocol [redacted] although this subject met protocol exclusion criteria 4.2.m, "History of two or more episodes of medically attended wheezing illness by parent/guardian report." The subject was randomized to the study on [redacted] In a Memo-To-File dated 10/3/02, you stated "The participant's first documented case of bronchiolitis occurred on [redacted] when the participant sought and received treatment in the Emergency Room. The second episode of wheezing occurred intermittently between [redacted] The third episode of wheezing occurred on [redacted] The sponsor instructed you to withdraw this subject on 9/26/02.

In your response letter, you agreed with this observation.

ii. You failed to obtain a rectal temperature for Subject [redacted] at the time of enrollment in study [redacted] Section I.D.2.e of protocol [redacted] excluded subjects experiencing "Fever, with a rectal temperature ≥ 38.1° C (100.5°F) at the time of immunization."

In your response letter, you admitted the temperature was not measured.

D. You failed to administer study vaccine to subjects within the timeframe required by the protocol. Protocol version [redacted] required an interval of 28 to 56 days between study vaccine doses. Protocol version [redacted] required an interval of 28 to 70 days between study vaccine doses. The following study vaccine doses were not administered, even though the subjects were seen at your office within the acceptable timeframe:

- you failed to administer the second dose of study vaccine to subject [redacted] at office visits on [redacted] and [redacted]
- you failed to administer the third dose of study vaccine to subject [redacted] at office visits on [redacted] and [redacted]
- you failed to administer the third dose of study vaccine to subject [redacted] at an office visit on [redacted]

By the time these errors were discovered, the subjects were ineligible to receive the next dose of study vaccine because you had exceeded the maximum protocol-specified timeframe.

Item 2.D. was not included on the Form FDA 483.

E. You administered study drug that had been stored at temperatures outside of the protocol-required range.

i. Section I.E.3.f of protocol [redacted] stated "Refrigerator temperatures from 0 to 8°C are acceptable for [redacted]/placebo storage. Should the refrigerator temperature reach about 8°C (46.4°F) or above, the SPONSOR should be notified immediately and the vaccine should not be used."

a. On 11/11/02, the maximum temperature of the refrigerator containing study drug was recorded on the "Daily Temperature Log" as 9°C. At the time of this temperature excursion, 19 vials of study drug were stored in the refrigerator. Per the sponsor's instructions, the vials were to be labeled "do not use." However, vial [redacted] was administered to subject [redacted] on [redacted]

In your response letter, you agreed with this observation.

b. The maximum refrigerator temperature of the refrigerator containing study drug was recorded on the "Daily Temperature Log" during the period 11/14/01 to 12/11/01 as 29°C. Study drug stored under these temperature conditions was administered to subject [redacted] on [redacted] Your staff did not recognize the violation. The sponsor's monitor discovered this temperature excursion during a monitoring visit.

In your response letter, you agreed with this observation.

ii. Section 9.6.1 of protocol [redacted] required that [redacted] and Placebo [redacted] be stored at -20°C or below with a variation of up to 5°C. Further, the Study Manual for Season 2 for Protocol [redacted] states "If any unit is not maintaining the appropriate temperature range for the vaccines stored, **immediately** alert [redacted] [Emphasis added]. The freezer log for this study documented temperatures out of specification on most days during the period from 10/16/02 to 11/26/02, when the maximum temperatures range from -5°to -14°C. Additionally, study vaccine stored in the freezer under out-of-specification temperatures recorded on 9/11/02 and 9/12/02 in the "State Temperature Log" was administered to subject [redacted] on [redacted] and to subject [redacted] on [redacted] These out-of-specification temperatures were not noticed until you were visited by the sponsor's monitor.

In your response letter, you explained that the temperature log required by the State of Massachusetts was not used as a study record, however, you recognize that "the state temperature log provides an independent measurement of the refrigerator/freezer temperature at the time measured" and the temperature readings indicate "a temperature outside of the protocol requirements."

F. Section 5.2.3.1 of protocol [redacted] states "After vaccination, a thermometer, daily safety assessment worksheets and instructions, along with a guide to measure the size of injection site reactions will be given to the parent/guardian." The parents/guardians of subjects [redacted] and [redacted] stated that they did not receive temperature instructions, a list of aspirin-containing medications, an injection site measuring guide, or thorough instructions regarding the collection of diary card information. The [redacted] Source document template/Visit 1" case report forms for these subjects incorrectly indicate that these items and instructions were supplied at Visit 1. In addition, the parent/guardian of subject [redacted] stated that she was not given a thermometer, even though the sponsor provided thermometers for each subject. These items were provided to the subjects' parents/guardians to assess and record reactogenicity events. You were required to provide the list of aspirin-containing medications to prevent the

parents/guardians from administering medications containing aspirin to the infant subjects while participating in the study.

Item 2.F. was not included on the Form FDA 483.

3. **You repeatedly submitted false information to the sponsor in a required report. [21 CFR § 312.70].**

You repeatedly submitted false information to the sponsor documenting the completion of post vaccination follow-up safety contacts for subjects enrolled in protocols [redacted] and [redacted] that were, in fact, not performed.

A. You submitted case report forms to the sponsors of studies [redacted] and [redacted] reporting that protocol required follow-up safety contacts were performed for subjects receiving study drug. However, in a Memo-To-File dated 1/9/03, you acknowledged that you contacted the parent or guardian of all currently active participants in study [redacted] (subjects [redacted] and determined that "without exception, these participants report that [redacted] the previous clinical research coordinator, did not perform the protocol specified safety contacts." Additionally, you documented in a Memo-To-File dated 11/27/02 for study [redacted] that "The data entered by the previous study coordinator in both the source documentation and the Case Report Forms cannot be verified." The following table lists the follow-up safety contacts that were required to have been performed as of the time studies [redacted] and [redacted] were halted.

Subject	Study	Safety Contacts That Were Required and Were Not Performed After the Following Dose(s):
[redacted]		1,2,3
		2
		1,2
		1
		1,2,3
		1

B. You submitted false post-vaccination temperature records to the sponsor for subject [redacted] in study [redacted] recorded on the [redacted] Source document template/Visit 1" on 11/25/02 that the parent of subject [redacted] reported that the child's temperature was obtained on only the first three days after the subject received the study drug. However, the case report form submitted to the sponsor purports that temperatures were recorded from Day 1 through Day 28.

Items 3.A. and 3.B. were not included on the Form FDA 483.

4. You failed to obtain informed consent in accordance with the provisions of 21 CFR Part 50. [21 CFR §§ 312.60 and 312.70].

A. Informed consent documents show different dates for the signatures of the parent/guardian, the person obtaining informed consent, and the witness other than the person obtaining informed consent.

i. The informed consent document approved by the IRB requires the dated signature of the parent/guardian, the person obtaining the informed consent, and a witness to the informed consent discussion. As shown in the table below, on some occasions, the "person obtaining consent" and/or the "witness" signed the informed consent document on a later date, signifying that they were not present for a discussion of the studies' risks and potential benefits. The purpose of the informed consent discussion is to explain the informed consent information, answer questions about the study, and to assess whether the parent/guardian has an understanding of the study.

In your response letter, you agreed with this observation.

Subject	Informed Consent Version	Date of Parent / Guardian signature	Date of person obtaining consent signature	Date of witness signature
[redacted]	6/05/01	11/27/01	11/27/01	**1/31/02**
	3/13/02	5/9/02	**6/5/02**	**6/5/02**
	6/05/01	2/25/02	2/25/02	**3/4/02**
	3/13/02	4/23/02	**9/19/02**	**6/5/02**
	3/13/02	4/30/02	**6/05/02**	4/30/02
	Template	**Did not date**	3/21/02	**No witness**
	3/13/02	5/20/02	**6/5/02**	5/20/02
	Template	3/21/02	3/21/02	**No witness**
	3/13/02	5/23/02	**6/13/02**	**6/13/02**
	3/13/02	7/13/02	**9/11/02**	**7/31/02**
	3/13/02	5/20/02	**6/13/02**	5/20/02
	5/30/02	8/22/02	**9/11/02**	8/22002

ii. In a "Note-To-File" dated 1/29/03, you documented that subinvestigator [redacted], in fact, did not witness two informed consent discussions for subject [redacted] yet she signed the 3/13/02 version of informed consent as the "Person Obtaining Consent," and signed the 5/30/02 version of informed consent as the "Witness Other Than Person Obtaining Consent" as if she had been present at the consent discussions.

Item 4.A.ii. was not included on the Form FDA 483.

B. You failed to provide study information in a language understandable to prospective study subjects, in order to ensure they were fully informed of the risks and potential benefits associated with the studies and understood their rights as study participants, in violation of 21 CFR § 50.20.

i. Section II.E of protocol [redacted] required that:

> The information from the consent form should be translated and communicated to the subject in language understandable to the subject. When the study subject population includes non-English speaking people, an accurately translated consent form should be provided with a written statement by the translator (whether the translator is the investigator, the Clinical Monitor, or a professional translator), indicating that the consent form is an accurate translation of the accompanying English version.

An informed consent document translated into Russian was not provided to the parent/guardian of subject [redacted] in study [redacted] although the parent did not have sufficient proficiency in English to communicate. In a Note-To-File dated 1/29/03, you documented that subinvestigator [redacted] orally presented "a general overview" of the study to the parent of subject [redacted] in Russian.

ii. An informed consent document translated into Chinese was not provided to the parent/guardian of subject [redacted] in study [redacted] When study coordinator [redacted] contacted the parent of subject [redacted] on 11/26/02 to obtain protocol required safety follow-up information, she documented in the [redacted] Source document template/Visit 2" that "the mother's command of English was not sufficient to conduct phone contact."

Items 4.B.i. and 4.B.ii. were not included on the Form FDA 483.

C. The parent/guardian signatures on at least two informed consent documents are not authentic signatures.

i. Two signed version 5/30/02 informed consent documents exist for subject [redacted] for study [redacted] Both consent documents are dated 9/11/02 and the name of the subject is spelled differently on each document. The signature on one of the consent documents does not appear to reflect the name or signature of the subject's mother or father.

In your response letter, you state that you believe that the informed consent document containing the correctly spelled subject's name and parent's signature is valid. You state that you will determine the validity of this document with the parent at the subject's next clinic visit. In your response to this letter, please report the outcome of your inquiry. In any event, even if one of the documents were to contain the correct parent's signature, the other document purports to contain a valid signed document when, in fact, it is not.

ii. The parent/guardian signature on the 5/30/02 version of informed consent for subject [redacted] in study [redacted] s not the signature of the subject's mother or father. In a Note-To-File dated 1/29/03, you state that the subject's mother was shown this informed consent document on 12/5/02, and she stated that the signature was neither her signature nor her husband's signature.

In your response letter, you acknowledged this falsification.

D. The informed consent document for subject [redacted] is dated 4/30/02, after the first dose of study drug was administered on [redacted] for study [redacted]

In your response letter, you explain that the subject provided informed consent on 3/4/02 using the 6/5/01 version of the informed consent document, however, this document has been misplaced. You subsequently obtained informed consent on 4/30/02 using the 3/13/02 version of the informed consent document. In Attachment 12 of your response letter, you state that the sponsor's monitor reviewed the 6/5/01 version of the informed consent document for this subject on 9/11/02. The monitor questioned the integrity of the document, because the signature of the parent appeared to have been traced. When the monitor returned to the site two days later, study coordinator [redacted] was unable to produce the document. According to your response letter, the document is still missing.

E. An informed consent document that had not been approved by the IRB was used to obtain consent in study [redacted] for subjects [redacted] and [redacted] on 3/21/02. The 6/5/01 IRB-approved version of the consent document was available to obtain the informed consent from these subjects.

In your response letter you acknowledge this violation.

F. You documented in a Note-To-File dated 11/14/02, that the following signed consent documents are missing, or informed consent was not updated using the following versions of the consent forms for study [redacted] 6/5/01 version for subjects [redacted] and [redacted] 3/13/02 version for subjects [redacted] and 5/30/02 version for subjects [redacted] and [redacted]

In your response letter, you acknowledge this violation.

G. You failed to provide a copy of the signed and dated informed consent document to the parent/guardian of six subjects enrolled in study [redacted] as required by 21 CFR § 50.27(a). Follow-up by the new study coordinator on 11/26/02 revealed that the parents/guardians of subjects [redacted] and [redacted] reported they did not receive a copy of the informed consent document for study [redacted] We note that the parent of subject [redacted] could not answer the new study coordinator's question regarding receipt of the informed consent document due to a language barrier, as referred to in item 3.B.ii. above. Subsequently, on 12/31/02, you sent each participant in study [redacted] a copy of an original, signed, informed consent document via certified mail as described in a Memo-To-File dated 12/31/02.

Item 4.G. was not included on the Form FDA 483.

5. **You failed to prepare and maintain adequate and accurate case histories recording all observations and other data pertinent to the investigation on each individual administered the investigational drug, including case report forms and supporting data. [21 CFR § 312.62(b)].**

A. You reported in the case report forms that post vaccination follow-up safety contacts were performed for subjects enrolled in studies [redacted] and [redacted] as required by the protocol, when, in fact, they were not performed. See item 3.A. above.

In your response letter, you agree with this observation for subjects [redacted] and [redacted]

Subjects [redacted] and [redacted] were not included on the Form FDA 483.

B. You failed to complete subjects' medical records as required by the "Minimal Charting Requirements for [redacted] Study," Study [redacted]. These requirements state "Notation must be entered in the chart describing the informed consent process. The following must be mentioned: Informed consent obtained from mother/father; All questions were answered; No study related procedure was conducted prior to obtaining consent; Signed and dated copy of the consent was given to mother/father." In addition, you were required to include the study vaccine identification number in the clinical chart. This required information was not documented in the medical charts of study subjects prior to November 1, 2002, with the exception of subject [redacted]

In your response letter, you state that you agree with this observation.

C. There are discrepancies between the "Vaccine Administration Record," "Vaccine Inventory and Label" case report form, [redacted] Study Checklist," and the medical records for subjects [redacted] and [redacted] for study [redacted] regarding the name of the individual administering study vaccine. According to the medical record, [redacted] administered study vaccine to subject [redacted] on [redacted] and [redacted] administered study vaccine to subject [redacted] on [redacted] as described in item 1.C. above. However, the name [redacted] appears on the "Vaccine Administration Record", "Vaccine Inventory and Label" case report form, and [redacted] Study Checklist" as the person administering study drug in study [redacted]

In your response letter you state that you agree with this observation for subjects [redacted] and [redacted]

On the basis of the above listed violations, FDA asserts that you have repeatedly or deliberately failed to comply with the cited regulations, and repeatedly submitted false information to the sponsor in a required report. Accordingly, FDA proposes that you be disqualified as a clinical investigator. You may reply to the above stated issues, including any explanation of why you believe you should remain eligible to use investigational drugs and not be disqualified as a clinical investigator, in a written response or at an informal conference in my office. This procedure is provided for by regulation 21 CFR § 312.70(a).

Within fifteen (15) days of receipt of this letter, write to me to arrange a conference time or to indicate your intent to respond in writing. Your written response must be forwarded within thirty (30) days of receipt of this letter. Your reply should be sent to:

James S. Cohen, J.D., Acting Director
Office of Compliance and Biologics Quality (HFM-600)
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, Maryland 20852-1448

Should you request an informal conference, we ask that you provide us with a full and complete explanation of the above listed violations. You should bring with you all pertinent documents, and you may be accompanied by a representative. Although the conference is informal, a transcript of the conference will be prepared. If you choose to proceed in this manner, we plan to hold such a conference within thirty (30) days of your request.

At any time during this administrative process, you may enter into a consent agreement with FDA regarding your future use of investigational products. Such an agreement would terminate this disqualification proceeding. Enclosed you will find a proposed agreement.

The Center will carefully consider any oral or written response. If your explanation is accepted by the Center, the disqualification process will be terminated. If your written or oral response to our allegations are unsatisfactory, or we cannot come to terms on a consent agreement, or you do not respond to this notice, you will be offered the opportunity to request a regulatory hearing before FDA, pursuant to 21 CFR Part 16 (available at the Internet address identified on page 1 of this letter) and 21 CFR § 312.70. Such a hearing will determine whether or not you will remain entitled to receive investigational products. You should be aware that neither entry into a consent agreement nor pursuit of a hearing precludes the possibility of a corollary judicial proceeding or administrative remedy concerning these violations.

Sincerely,

James S. Cohen, J.D.
Acting Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

cc: [redacted]

Enclosures: Proposed consent agreement
Form FDA 1572