SMG 7715

FDA Staff Manual Guides, Volume IV – Agency Program Directives

Compliance Activities

FDA Consideration of Reinstatement Requests from Disqualified Clinical Investigators

Effective Date: 09/02/2021

1. Purpose

The purpose of this Staff Manual Guide (SMG) is to describe the procedures to be followed when a disqualified clinical investigator requests to be reinstated as eligible to receive test articles under 21 CFR parts 312, 511, and/or 812 and to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

2. Policy

A. FDA is committed to responding promptly to requests for reinstatement.

B. All involved parties should be kept informed throughout the process.

C. The Center that initiated the disqualification proceedings against a clinical investigator reviews requests for reinstatement and provides a recommendation as to whether a disqualified clinical investigator should be reinstated.

D. A Reinstatement Committee reviews and evaluates Center recommendations for each reinstatement request.

E. The Chief Scientist has oversight over the reinstatement process.

F. The Office of Scientific Integrity manages the reinstatement process.

G. Reinstatement Committee reports and Chief Scientist decisions regarding reinstatement requests should be shared with all Centers and the Office of Regulatory Affairs.

H. Reinstatement decisions by the Chief Scientist should be posted on the FDA Clinical Investigators Disqualification Proceedings webpage.[1]

I. All timeframe references are to calendar days**,** unless stated otherwise**.**

3. Definitions[2]

A. Adequate Assurances. Assurances provided by a disqualified clinical investigator seeking reinstatement that the investigator will employ all test articles and will conduct any investigation that supports an application for a research or marketing permit for products regulated by FDA solely in compliance with applicable regulations. (see 21 CFR 312.70(f), 21 CFR 511.1(c)(6), and 21 CFR 812.119(f)).

B. Center(s). One or more of FDA's Centers, e.g., Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), and Center for Veterinary Medicine (CVM).

[1] FDA's Clinical Investigators Disqualification Proceedings webpage includes a public database of all of the clinical investigators who are or have been subject to an administrative clinical investigator disqualification action and indicates the current status of that action. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/clinical-investigators-disqualification-proceedings

[2] Note that these definitions are provided solely for the purposes of this document.

C. **Chief Scientist**. The deciding official for reinstatement requests from disqualified clinical investigators. The Chief Scientist has the delegated authority to perform all delegable functions of the Commissioner of Food and Drugs (see SMG 1410.21(1)(B)(7)). There may be occasions when another FDA official acts on behalf of the Commissioner with respect to the responsibilities outlined for the Chief Scientist in this SMG. For the sake of efficiency, this SMG nonetheless refers to the deciding official in reinstatement matters as the Chief Scientist.

D. **Clinical Investigator.** An individual who receives test articles under 21 CFR 312, 511, or 812 and/or conducts any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

E. **Compliance Management System or CMS**. Compliance Management System is a web-based application consisting of a collection of modules supporting Agency compliance management and workflow for compliance-related activities.

F. **Disqualification.** An agency-level determination—or consent agreement reflecting an agreement between an individual and a Center—that the individual is ineligible to serve as a clinical investigator (see 21 CFR 312.70(b), 511.1(c)(2) and 812.119(b)).

G. **Disqualified Clinical Investigator.** An individual who is ineligible to serve as a clinical investigator as a result of disqualification.

H. **Office of Regulatory Affairs or ORA**. The lead office for all agency field activities, including inspections related to clinical investigations, which assists the Centers in implementing aspects of disqualification and reinstatement.

I. **Office of Scientific Integrity or OSI.** The office within the Office of the Chief Scientist, Office of the Commissioner that is responsible for managing the reinstatement process for disqualified clinical investigators.

J. **Reinstatement**. An agency-level determination that an individual, who would otherwise be a disqualified clinical investigator, has presented adequate assurances that he or she will employ test articles solely in compliance with the applicable regulatory provisions (see 21 CFR 312.70(f), 511.1(c)(6), and 812.119(f)) and is therefore eligible to serve as a clinical investigator under the terms and conditions of any applicable Reinstatement Agreement.

K. **Reinstatement Agreement.** A written agreement between FDA and a clinical investigator in which the disqualified clinical investigator agrees to certain terms and conditions in order to be eligible to receive investigational articles and conduct a clinical investigation.

L. Reinstatement Committee. An *ad hoc* committee comprising representatives from the Centers and the Office of Regulatory Affairs (ORA) convened by the Office of the Chief Scientist to review and evaluate a Relevant Center's recommendation regarding a request for reinstatement from a disqualified clinical investigator.

M. Reinstatement Request. A written, formal request by a disqualified clinical investigator for reinstatement.

N. Relevant Center. The Center that initiated disqualification proceedings with respect to a disqualified clinical investigator who has submitted a reinstatement request.

4. Background

A clinical investigator who has been disqualified under FDA regulations is not eligible to receive test articles or to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.[3]

A disqualified clinical investigator may request to be reinstated as eligible to receive test articles and to conduct FDA-regulated clinical investigations by presenting "adequate assurances" that the investigator will employ all test articles and will conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA solely in compliance with applicable regulations.[4]

FDA will determine, based on information in the administrative record of the original disqualification, materials submitted with the reinstatement request in support of the disqualified clinical investigator's assertion of adequate assurances, and other information, as deemed appropriate, whether the disqualified clinical investigator can be reinstated.

5. Application

This SMG sets forth the agency's process for addressing requests for reinstatement submitted by disqualified clinical investigators.

Note that this SMG does <u>not</u> apply to requests from clinical investigators who are seeking agency action related to restricted agreements.[5] As set forth in SMG 7713

[3] 21 CFR 312.70(b), 511.1(c)(2), and 812.119(b)
[4] 21 CFR 312.70(f), 511.1(c)(6), and 812.119(f)

[5] *See* Clinical Investigators – Disqualification Proceedings webpage: https://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true

("Clinical Investigator Restricted Agreement Compliance and Change in Status from 'Restricted' to 'Restrictions Removed'"), a "restricted agreement" is:

> A negotiated and agreed upon set of terms and conditions (including any exhibits, appendices, addendums, schedules, and amendments) between FDA and a clinical investigator that sets forth certain restrictions or conditions the parties agree to pertaining to the investigator's participation in, or conduct of, clinical investigations of FDA-regulated test articles, offered to the investigator at the discretion of FDA after the initiation of a disqualification proceeding. Restricted agreements generally include performance measures to enable the Center to assess compliance with the agreement and to help ensure clinical investigator compliance with applicable laws and regulations.[6]

Insofar as a clinical investigator's submission relates to removal from a restricted agreement, agency staff should follow SMG 7713.

6. Responsibilities and Procedures

A. General responsibilities

1. The Chief Scientist oversees the reinstatement process for FDA and renders decisions for the agency on reinstatement requests, after considering recommendations from the Relevant Center and a Reinstatement Committee.

2. OSI is responsible for coordinating—and maintaining records regarding—the reinstatement process with respect to disqualified investigators.

3. The Relevant Center's general responsibilities include:

    a. Obtaining appropriate clearance by FDA's Office of the Chief Counsel (OCC) for actions (including documents implementing such actions) taken in accordance with the Center's responsibilities in this Guide,

    b. Evaluating reinstatement requests and developing a recommendation with respect to the disposition of those requests for submission to the Reinstatement Committee and ultimate consideration by the Chief Scientist,

[6] https://www.fda.gov/media/84895/download at 2.

c. Maintaining the records regarding internal Center deliberations related to those recommendations,

d. Nominating a qualified Center representative to serve as both:

(i) a point of contact for OSI and the Reinstatement Committee; and
(ii) a non-deliberating representative to attend meetings of the Reinstatement Committee.[7]

e. Providing, as appropriate, information about clinical investigator reinstatements to ORA to update the FDA Clinical Investigators Disqualification Proceedings webpage.[8]

4. Centers that were not involved in initiating the original disqualification proceedings are responsible for nominating qualified representatives to serve as members on the Reinstatement Committee for reinstatement requests from disqualified investigators, with appropriate consideration given to availability and any previous involvement with the relevant disqualification proceedings or the disqualified investigators.

5. ORA's responsibilities include:

a. Conducting inspections and investigations, as necessary and pursuant to issuance of an inspection assignment from the Relevant Center, to evaluate whether reinstated investigators are in compliance with all applicable laws and the terms and conditions of any applicable Reinstatement Agreement,

b. Nominating two representatives to serve as members on Reinstatement Committees, one each from the Office of Strategic Planning and Operational Policy (OSPOP) Division of Enforcement (DE) and the Office of Bioresearch Monitoring Operations (OBIMO), with appropriate consideration given to availability and any previous involvement with the relevant disqualification proceedings or the disqualified investigators.

B. Procedures

[7] Any substantive communications between OSI and the Relevant Center's point of contact or between the Reinstatement Committee and the point of contact—when not occurring during a meeting of the Reinstatement Committee—should be memorialized in writing and uploaded to CMS.

[8] https://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true

1. Agency personnel should direct all disqualified investigators seeking to submit reinstatement requests to address such requests to the Chief Scientist and submit such requests to the Office of Scientific Integrity at this email address: ococsappeals@fda.hhs.gov.

   In the event that agency personnel other than those in OSI receive a reinstatement request, they should (a) forward the reinstatement request, including all attachments, to OSI at the foregoing email address; or, if the submission was made by mail, (b) scan the reinstatement request, including all attachments, send the electronic documents to OSI via email and send the original hardcopy reinstatement request, including all attachments, to:

   Director, Office of Scientific Integrity
   Office of the Chief Scientist
   Food and Drug Administration
   10903 New Hampshire Avenue
   Silver Spring, MD 20993-0002

2. Upon receipt of the reinstatement request, OSI should:

   a. Log the date of receipt and the letter requesting reinstatement, along with any attachments, into CMS and create a file in CMS for the reinstatement request;

   b. Within seven (7) days, send an acknowledgement letter to the disqualified investigator that the request was received by FDA (Attachment A);

   c. Within seven (7) days, forward the reinstatement request, including all attachments, via email to the Relevant Center at an address designated by that Center for receiving such requests; and

   d. Within ninety (90) days:
      (i) begin convening a Reinstatement Committee by requesting nominations for one member each from Centers other than the Relevant Center and ORA's OSPOP/DE and OBIMO at addresses designated by those components for requesting such nominations, and
      (ii) seek a nomination from the Relevant Center for an individual to serve as a point of contact and a non-deliberating member of the Reinstatement Committee.

3. Within 120 days of receiving the reinstatement request from OSI, the Relevant Center should review and evaluate the reinstatement request and

finalize a recommendation to the Chief Scientist. The Relevant Center should send the recommendation to OSI via email and also upload the recommendation into CMS:

a. If the Relevant Center requires additional information from the disqualified clinical investigator to evaluate the reinstatement request, the Center should notify OSI and ask OSI to make a written request for such information to the disqualified clinical investigator; the request should include a deadline for responding to the request; the 120 days should be tolled until either the deadline has expired or the disqualified clinical investigator has responded, either by supplying the requested information or by explicitly indicating that he or she will provide no additional information, whichever occurs earlier;

b. If the recommendation to the Chief Scientist is to deny the reinstatement request, the recommendation should include a detailed and comprehensive explanation for such recommendation, with citation to:
(i) specific aspects of the administrative file of the disqualification proceedings,
(ii) the materials submitted in connection with the reinstatement request, and
(iii) any other information deemed appropriate by the Relevant Center; the recommendation must also include as attachments all documents cited (including screenshots of any cited webpages);

c. If the recommendation to the Chief Scientist is to grant the reinstatement request, the recommendation should include:
(i) a detailed and comprehensive explanation for such recommendation with citation to:
(A) specific aspects of the administrative file of the disqualification proceedings,
(B) the materials submitted in connection with the reinstatement request, and
(C) any other information deemed appropriate,; the recommendation must also include as attachments all documents cited (including screenshots of any cited webpages);
(ii) a proposed reinstatement agreement with all recommended terms and conditions for reinstatement, as cleared by the Center and OCC;

d. In addition to submitting the recommendation to OSI via email, the Relevant Center should upload documents into CMS to ensure

that OSI has access to the administrative record for the original disqualification proceedings, all correspondence between Center personnel and the disqualified clinical investigator with respect to the reinstatement request, and any materials submitted by the disqualified clinical investigator to the Center in connection with the reinstatement request on his or her own initiative or at the request of the Center.

4. Within ninety (90) days of a recommendation from the Relevant Center being made available to OSI, the Reinstatement Committee should finalize a report for submission to the Chief Scientist.

    a. OSI should disseminate all relevant materials, including the Relevant Center's recommendation regarding the reinstatement request, to the Reinstatement Committee.

    b. OSI should coordinate and oversee at least one meeting of the Reinstatement Committee at which a majority of members discuss the substance of the Relevant Center's recommendation and appropriate considerations, including the terms and conditions described in the proposed Reinstatement Agreement; additional representatives from the Centers and ORA may attend Reinstatement Committee meetings to observe the proceedings or answer questions about the recommendation and the terms of the Reinstatement Agreement but will not participate in the discussion regarding the recommendation;

    c. Committee members are responsible for familiarizing themselves with the Relevant Center's recommendation and other relevant materials provided by OSI before the meeting(s) to deliberate;

    d. OSI should assist the Reinstatement Committee in drafting a report:
        (i) the report should reflect the views of *all* members of the Committee, including all dissenting views, on whether the Relevant Center's recommendation should be adopted in whole or in part, including any revisions to the Reinstatement Agreement recommended by any member of the Reinstatement Committee;
        (ii) the Reinstatement Committee should adopt the report by unanimous vote, except members may affirmatively opt to abstain from the vote (as must be memorialized in the report and recommendation);
        (iii) the views of the representative from the Relevant Center will not be reflected in the report, though the report will

document any answers to questions deemed pertinent to the Reinstatement Committee's report, and

(iv) the report will incorporate by reference, in whole or in part, the Relevant Center's recommendation;

e. OSI should convey the report to the Chief Scientist as soon as practicable after finalization by the Reinstatement Committee.

5. Within sixty (60) days of receiving the Reinstatement Committee's report, the Chief Scientist should propose a written decision with respect to the reinstatement request, and OSI should upload the proposed decision to CMS:

   a. the Chief Scientist's proposed written decision will provide a detailed explanation for the outcome, including an analysis of the terms and conditions of any reinstatement, and may adopt, as appropriate, aspects of either or both the Relevant Center's recommendation and the Reinstatement Committee's report but will not incorporate either by reference,

   b. if the proposed decision would grant reinstatement pursuant to the Relevant Center's recommendation but would modify the Relevant Center's recommended Reinstatement Agreement, the proposed decision will also include as an attachment a copy of the proposed revised Reinstatement Agreement,

   c. if the proposed decision would reject the Center's recommendation to deny reinstatement and grant the reinstatement request, the proposed decision will include language remanding the matter to the Center for generation of a Reinstatement Agreement consistent with the decision.

6. Within fourteen (14) days of receipt of the Chief Scientist's proposed decision, if the Relevant Center wishes to request modifications to either the Chief Scientist's proposed decision or any proposed revised Reinstatement Agreement, the Relevant Center should upload to CMS:

   (a) a written request for modification(s), which must include a summary of the requested changes and an explanation therefor, and (b) a redline version of the Chief Scientist's proposed decision and any proposed revised Reinstatement Agreement; if the Relevant Center requires additional time to provide such a request for modification(s), the Relevant Center may seek an extension of time from OSI.

7. As soon as practicable but no later than thirty (30) days after either the opportunity for the Relevant Center to upload a request for modification(s) expires or when the Relevant Center uploads a request for modification(s)—whichever occurs earlier—the Chief Scientist should finalize his or her written decision:

    a. if the Chief Scientist has adopted the Relevant Center's recommendation to grant reinstatement or has denied reinstatement, the Chief Scientist should issue the decision to the clinical investigator, and OSI should upload the decision to CMS,

    b. if the decision grants reinstatement, the decision will include a copy of the proposed Reinstatement Agreement and provide a deadline of thirty (30) days to sign the Reinstatement Agreement and return it to the point of contact at the Relevant Center;[9]

    c. if the Chief Scientist has rejected the Relevant Center's recommendation to deny reinstatement and intends to grant reinstatement:
        (i) as soon as practicable, OSI should upload the decision to CMS,
        (ii) within sixty (60) days, the Relevant Center should upload to CMS a proposed Reinstatement Agreement consistent with the Chief Scientist's decision, and
        (iii) within (30) days of the receiving the proposed Reinstatement Agreement, the Chief Scientist should: (A) finalize his or her written decision, (B) direct OSI to upload the decision to CMS, and (C) issue the written decision, along with a Reinstatement Agreement, to the reinstated clinical investigator and provide a deadline of thirty (30) days to sign the Reinstatement Agreement and return it to the point of contact at the Relevant Center.

8. The Relevant Center will implement the Chief Scientist's decision.

    a. If the Chief Scientist's decision is to reinstate the disqualified clinical investigator:
        (i) the Relevant Center should monitor whether the disqualified clinical investigator signs and returns the Reinstatement Agreement to the Relevant Center's point of contact within the thirty-day deadline prescribed by the Chief Scientist's decision but may extend the deadline by up to sixty (60) days,

[9] Any final decision communicated to the clinical investigator in accordance with this Guide must be memorialized in writing and sent to the investigator by means enabling confirmation of delivery.

(ii) the Relevant Center should work with the disqualified clinical investigator (through OCC, as appropriate) to make any minor adjustments to the Reinstatement Agreement required by unanticipated practical considerations, as requested by the disqualified clinical investigator, and obtain concurrence from the Office of the Chief Scientist,
(iii) if the disqualified clinical investigator fails to sign the agreement within thirty (30) days—or within any additional time authorized by the Relevant Center—the Relevant Center may withdraw the Reinstatement Agreement, and the disqualified clinical investigator's status will remain "Disqualified" on the FDA Clinical Investigators Disqualification Proceedings webpage,[10] and
(iv) upon execution of the agreement by the reinstated clinical investigator and the Relevant Center, the Relevant Center will work with ORA's OSPOP/DE to update the FDA Clinical Investigators Disqualification Proceedings webpage to change the clinical investigator's status from "Disqualified" to "Reinstated pursuant to Agreement" and, after consulting with the Relevant Center FOI office as to disclosure issues and appropriate redactions of confidential commercial or privacy information, to post the Chief Scientist's decision to the same webpage;

b. If the Chief Scientist's decision is to deny reinstatement, the Relevant Center will work with ORA's OSPOP/DE to post the decision to the FDA Clinical Investigators Disqualification Proceedings webpage after consulting with the Relevant Center FOI office as to disclosure issues and appropriate redactions of confidential commercial or privacy information, but there will be no change to the disqualified clinical investigator's status on that webpage.

9. For any clinical investigator currently under a reinstatement agreement, the Relevant Center and ORA should work together to determine whether the clinical investigator is complying with the terms and conditions of any Reinstatement Agreement, including evaluating reports and updates from the clinical investigator and conducting inspections, as resources permit and as warranted, consistent with any Reinstatement Agreement and the agency's inspectional authorities.

10. The Relevant Center is responsible for determining whether to pursue rescission of reinstatement related to any violation(s) of the terms and

[10] https://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true

conditions of the Reinstatement Agreement. The Relevant Center may base any such determination on any available information (such as that received through reports, inspections or otherwise).

a. The Relevant Center should draft a letter to the reinstated clinical investigator notifying the investigator of its proposal to rescind the reinstatement agreement, setting forth the grounds for rescission and providing a deadline of thirty (30) days for the clinical investigator to respond:
   (i) the Relevant Center should forward the draft letter and any supporting documents to OSI via email and also upload in CMS,
   (ii) within thirty (30) days of the receiving the draft letter, OSI should notify the Relevant Center whether the Chief Scientist concurs with the proposal to rescind, as drafted or with suggested or required revisions, or does not concur with the proposal:
      - if the Chief Scientist concurs with the proposal to rescind, the Relevant Center should send the proposed rescission letter with any required revisions to the reinstated clinical investigator, and upload the letter into CMS,
      - if the Chief Scientist does not concur with the proposal to rescind, OSI will communicate this decision in writing via email and CMS, but only after the providing the Relevant Center with an opportunity to discuss the reasons for non-concurrence with OSI and the Chief Scientist,
      - if OSI requests additional information from—and/or a meeting with—the Relevant Center in evaluating the proposal to rescind, the thirty (30) days will be tolled while the Relevant Center responds to the request or until the meeting occurs.

b. Within sixty (60) days after the Relevant Center receives a response from the clinical investigator or the opportunity to respond to the letter lapses, the Relevant Center should either:
   - issue a letter to the clinical investigator that revokes the proposal to rescind reinstatement, copy OSI, and upload the letter to CMS, or
   - send to OSI via email (and upload into CMS) a draft written decision for the Chief Scientist that rescinds the reinstatement, which decision should include analysis addressing any arguments raised in the reinstated clinical investigator's response.

c. Within forty-five (45) days after OSI receives the draft letter, the Chief Scientist should either:
   (i) finalize the rescission letter drafted by the Relevant Center by signing and issuing it to the clinical investigator, and copying the Relevant Center, or
   (ii) issue a decision letter to the reinstated clinical investigator revoking the proposal to rescind, copying the Relevant Center.

   In issuing either letter, the Chief Scientist and OSI may consult with the Relevant Center to obtain comments and other feedback and should do so in all cases before issuing a decision revoking the proposal to rescind. OSI will upload the final decision letter to CMS.

d. If the Relevant Center's proposal to rescind a clinical investigator's reinstatement results in rescission, the Relevant Center should within seven (7) days, work with ORA's OSPOP/DE to update the FDA Clinical Investigators Disqualification Proceedings webpage to change the clinical investigator's status from "Reinstated pursuant to Agreement" to "Disqualified, Reinstatement Rescinded" and to post the agency-level decision on such rescission to that same webpage; otherwise, there will be no change to the clinical investigator's status on the webpage.

11. If a Reinstatement Agreement provides for the possibility of releasing the clinical investigator from the Reinstatement Agreement upon request by the clinical investigator and demonstration of satisfactory completion of the terms of the agreement, the Relevant Center, after obtaining concurrence from the Chief Scientist, may grant or deny such request via a written decision to such effect in accordance with the terms and conditions of the Reinstatement Agreement; the Relevant Center should upload the written decision to CMS.

    If release from the Reinstatement Agreement is granted, the Relevant Center should work with ORA's OSPOP/DE to update the FDA Clinical Investigators Disqualification Proceedings webpage to change the clinical investigator's status from "Reinstated pursuant to Agreement" to "Reinstated" or some other term established under the terms and conditions of the Reinstatement Agreement.

7. Effective Date

The guide is effective September 2, 2021.

8. Document History – SMG 7715, "FDA Consideration of Reinstatement Requests from Disqualified Clinical Investigators"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	Sept. 2, 2021	N/A	OC/OCS	Denise Hinton, Chief Scientist

Attachment A

[Receipt of Request for Reinstatement under 21 CFR [312.70, or 511.1(c), or 812.119]]

[DATE]

[INVESTIGATOR]

[Address]

[INVESTIGATOR'S COUNSEL]

[Address]

Re: Receipt of Request for Reinstatement under 21 CFR [312.70, or 511.1(c), or 812.119]

Dear [INVESTIGATOR] [and/or INVESTIGATOR'S COUNSEL]:

The purpose of this letter is to acknowledge receipt of your request, under 21 CFR [312.70, or 511.1(c), or 812.119], for reinstatement of your eligibility to receive test articles and to conduct clinical investigations of FDA- regulated products. The Office of Scientific Integrity within the Office of the Commissioner has begun processing your request.

Sincerely,

Director, FDA Office of Scientific Integrity

Cc: [Relevant Center]

Bcc:

CDER: CDEROSIPMTRACK@fda.hhs.gov

CBER: CBERBIMONotification@fda.hhs.gov

CDRH: BIMO mailbox (BIMO-CDRH@fda.hhs.gov)

CTP: CTP-BIMO@fda.hhs.gov

CVM: Director of the Division of Compliance: Eric.Nelson@fda.hhs.gov
Deputy Director of Compliance: Amber.McCoig@fda.hhs.gov
CVM BIMO mailbox at: CVMBIMORequests@FDA.HHS.GOV

OGCP: gcpquestions@fda.hhs.gov

ORA: Program Director, OBIMO: Chrissy.Cochran@fda.hhs.gov
ORA BIMO mailbox
ORA OSPOP ENFORCEMENT Div ALL
oraospopenforcementdivall@fda.hhs.gov

CFSAN: CFSANBIMO@fda.hhs.gov

OCC: Send to relevant party in OCC at firstname.lastname@fda.hhs.gov

Attachment B

[Request for Additional Information in support of Reinstatement Request]

[DATE]

[INVESTIGATOR]

[Address]

[INVESTIGATOR'S COUNSEL]

[Address]

Re: Request for Additional Information regarding Request for Reinstatement under 21 CFR [312.70, or 511.1(c), or 812.119]

Dear [INVESTIGATOR] [and/or INVESTIGATOR'S COUNSEL]:

The purpose of this letter is to request that you submit additional information in support of your request, under 21 CFR [312.70, or 511.1(c), or 812.119], for reinstatement of your eligibility to receive test articles and to conduct clinical investigations of FDA regulated products. Please supply the following information: <*include list*>
You should send the requested information in electronic form to ococsappeals@fda.hhs.gov.If you are unable to send the materials electronically, you should send them to:

Director, Office of Scientific Integrity
Office of the Chief Scientist
Food and Drug Administration
White Oak Bldg. 1
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Sincerely,

Director, FDA Office of Scientific Integrity

Bcc: (see bcc list in Attachment A)

Attachment C

[Notice to Disqualified Clinical Investigator that Reinstatement Request is Denied]

[DATE]

[INVESTIGATOR]

[Address]

[INVESTIGATOR'S COUNSEL]

[Address]

Re: Denial of Request for Reinstatement under 21 CFR [312.70, or 511.1(c), or 812.119]

Dear [INVESTIGATOR] [and/or INVESTIGATOR'S COUNSEL]:

Under the authority delegated to me by the Commissioner of Food and Drugs, I have determined that your request for reinstatement under 21 CFR [312.70, or 511.1(c), or 812.119] is denied. I have determined that you have failed to present adequate assurances that you will employ all test articles and will conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA solely in compliance with FDA regulations.

My decision is based on the following <*provide the rationale for the decision*>

Sincerely,

[NAME]

Chief Scientist, Food and Drug Administration

Cc: [Relevant Center]

Bcc: (see bcc list in Attachment A)

Attachment D

[Notice to Disqualified Clinical Investigator that Reinstatement Request is Granted, Contingent on Entering into Reinstatement Agreement]

[DATE]

[INVESTIGATOR]

[Address]

[INVESTIGATOR'S COUNSEL]

[Address]

Re: Approval of Request for Reinstatement under 21 CFR [312.70, or 511.1(c), or 812.119.] Contingent on Reinstatement Agreement

Dear [INVESTIGATOR] [and/or INVESTIGATOR'S COUNSEL]:

Under the authority delegated to me by the Commissioner of Food and Drugs, I have determined that your request for reinstatement under 21 CFR [312.70, or 511.1(c), or 812.119] is granted, contingent upon your agreement to enter into a Reinstatement Agreement with FDA. The attached agreement includes "Terms of Reinstatement," including your acceptance of the condition that failure to abide by the stated terms will, of itself, be a basis for disqualification, without further proof that you repeatedly or deliberately failed to comply with the regulations for investigational studies.

Please sign and return the signed agreement to < *Relevant Center*> within thirty days of the date of this letter.

Sincerely,

[NAME]

Chief Scientist, Food and Drug Administration

Attachment: Reinstatement Agreement

Cc: [Relevant Center]

Bcc: (see bcc list in Attachment A)