

**FDA STAFF MANUAL GUIDES, VOLUME IV – AGENCY PROGRAM
DIRECTIVES**

COMPLIANCE ACTIVITIES

**DISQUALIFICATION OF A CLINICAL INVESTIGATOR: THE HEARING
PROCESS**

Effective Date: 08/25/2014

1. Purpose
2. Policy
3. Definitions
4. Background
5. Responsibilities and Procedures
 - A. The Clinical Investigator's Response to NOOH
 - B. A Part 16 Hearing
 - C. Commissioner's Decision
 - D. Administrative Record and Posting of Documents
6. Effective Date
7. History
 - Attachment A - Notice to a Party under 21 CFR 16.26(c) of Issuance of Presiding Officer Report (Letter)
 - Attachment B - Notice to a Party under 21 CFR 16.60(e) of Issuance of Presiding Officer Report (Letter)
 - Attachment C - Notice of Denial of Hearing and Disqualification (Letter)
 - Attachment D - Notice of Continuation of Eligibility to Receive (Letter)
 - Attachment E - Notice of Disqualification (Letter)
 - Attachment F - Routing/Clearance, Center Decision Memorandum
 - Attachment G - Commissioner's Decision (Memorandum)
 - Attachment H - Commissioner's Decision (Letter)
 - Attachment I - Notice to Sponsor of Investigator's Disqualification (Letter)

Attachment J - Notice to Institutional Review
Board of Investigator's Disqualification
(Letter)

1. PURPOSE

The purpose of this Staff Manual Guide (SMG) is to provide procedures for FDA staff to follow when a clinical investigator requests a hearing on a regulatory action to determine whether the investigator is eligible to receive test articles under 21 CFR Parts 312, 511, or 812 and whether the investigator is eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA (21 CFR Part 16, Regulatory Hearing before the Food and Drug Administration). This process will occur only after a Center has initiated disqualification proceedings under 21 CFR 312.70, 511.1(c), or 812.119, and the Associate Commissioner for Regulatory Affairs (ACRA) has issued a Notice of Opportunity for Hearing (NOOH). Adherence to the procedures described in this document will help ensure that disqualification actions are processed consistently and efficiently.

2. POLICY

- FDA is committed to completing the Part 16 hearing in a timely manner.
- All involved parties should be kept informed throughout the process.
- The option of entering into a consent agreement with the agency is available to the clinical investigator at any time throughout the process up to the issuance of the Commissioner's Decision under 21 CFR 16.95 or issuance of a notification of disqualification under 21 CFR 312.70, 511.1(c), or 812.119.¹
- The Commissioner has delegated the authority to perform his or her functions to the officials listed in Staff Manual Guide (SMG) 1410.21. This includes the authority to determine the eligibility of a clinical investigator to receive test articles and to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA. The term "Commissioner" in this document includes the Commissioner's delegate.

¹ A consent agreement may be signed by an FDA official according to the delegation of authority in Staff Manual Guide 1410.21, paragraph 1.P.

See

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM273783.pdf>.

- To determine the proper routing of documents, the Project Manager in the Office of Good Clinical Practice (OGCP) should be consulted. The Center should attach to the documents a cover memo or routing and transmittal form indicating the time by which the action should be completed, as recommended in this SMG.
- All timeframe references are to **calendar days**, unless stated otherwise.

3. DEFINITIONS

- A. Commissioner.** Commissioner includes the Commissioner of Food and Drugs and those officials delegated the authority to issue the final decision regarding the disqualification of a clinical investigator as listed in SMG 1410.21.²
- B. Director, Division of Enforcement (DE), Office of Enforcement and Import Operations (OEIO), Office of Operations (OO), Office of Regulatory Affairs (ORA), Office of Global Regulatory Operations and Policy (OGROP).** The Director, DE, is responsible for reviewing and issuing the NOOH with the signature of the ACRA, and coordinating actions related to the investigator's initial response to the NOOH.
- C. Deliberate Violation.** A willful action that need not entail knowledge that it is a violation of law as long as there is some perception of wrongdoing or of reckless disregard for obvious or known risks.³
- D. Disqualification of a Clinical Investigator.** A process through which a decision is made that a clinical investigator is ineligible to receive test articles under 21 CFR Parts 312, 511, or 812, and ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.
- E. Investigator (21 CFR 312.3 and 21 CFR 812.3(i)).** An individual who actually conducts a clinical investigation, i.e., under whose immediate direction the investigational test article is administered or dispensed to, or used involving, a subject, or in the event of an investigation conducted by a team of individuals, is the responsible leader of the team.⁴

² See <http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm049543.htm>.

³ See Report of the Presiding Officer, In the Matter of Huibert M. Vriesendorp, M.D. (2001), findings adopted by the Commissioner (2001); Report of the Presiding Officer, In the Matter of James A. Halikas 2000), findings adopted by the Commissioner (2001); Report of the Presiding Officer, In the Matter of John H. Hopkinson III, M.D. (1982), p. 10 (citing Report of the Presiding Officer, In the Matter of Martin S. Mok, M.D. (1982), pp. 5-6).

⁴ This SMG also applies to clinical investigators who investigate investigational new animal drugs. Although 21 CFR 511 does not define "investigator," sponsors may ship investigational new animal drugs only to investigators who are "qualified by scientific training and experience to evaluate the safety and/or effectiveness of the new animal drug" (21 CFR 511.1(b)(7)(i)).

- F. Motion for Summary Decision.** A motion with accompanying memorandum filed with the Presiding Officer explaining the issues in the proceeding and requesting a determination. The determination, also known as a Summary Decision, will be incorporated in the Presiding Officer's Report.
- G. Presiding Officer.** An official to whom the Commissioner delegates authority to conduct a regulatory hearing,⁵ or consistent with 5 CFR 930.209(b) or (c), an administrative law judge to whom such authority is delegated (21 CFR 16.42).
- H. Repeated Violation.** More than one violation, including the same violation, in one or more studies.⁶
- I. Separation of Functions.** Under separation of functions, agency personnel who are involved in advocating a proposed regulatory action (disqualification) do not participate in the agency's decision on the action. Upon receipt of a written request for a Part 16 hearing, the agency observes separation of functions, even though under 21 CFR 16.44(a), regulatory hearings are not subject to the separation of functions rules in 21 CFR 10.55. The principal purposes of observing separation of functions are to ensure fairness, to ensure that both sides have equal access to the decision-maker, and that neither can be accused of exerting improper influence. Separation of functions also ensures the independence of the decision-maker and that the decision is based only on the record and not on information that might have come to the attention of the decision-maker in some other way. The agency's adherence to separation of functions in investigator disqualification part 16 hearing proceedings has been adopted as a matter of policy.

⁵ See SMG 1410.29, 1.B.,

(<http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm049562.htm>).

⁶ See Report of the Presiding Officer, In the Matter of James A. Halikas (2000), findings adopted by the Commissioner (2001); Report of the Presiding Officer, In the Matter of Chaovane Aroonsakul, M.D. (1990), findings adopted by the Commissioner (1991); Report of the Presiding Officer, In the Matter of Ronald R. Fuller, D.V.M (1987), findings adopted by the Commissioner (1988); Report of the Presiding Officer, In the Matter of Stephen Steen, M.D., at 25 ("I do not interpret the term, 'repeated,' to require proof of violations in two different studies") (1982), findings adopted by the Commissioner (1984); Report of the Presiding Officer, In the Matter of John H. Hopkinson III, M.D. (1982), findings adopted by the Commissioner (1983); Report of the Presiding Officer, In the Matter of Michael C. Gelfand, M.D. (1980), findings adopted by the Commissioner (1981).

4. BACKGROUND

- Under its inspectional authority, FDA inspects a clinical trial site including the records of a clinical investigator, to evaluate the quality and integrity of clinical data used to support applications under review by FDA and to evaluate whether protection is afforded to participating research subjects. The inspection evaluates the clinical investigator's compliance with regulations governing the conduct of clinical trials (see 21 CFR Parts 50, 54, 56, 312, 511, and 812).
- FDA may consider disqualification of a clinical investigator (including a sponsor-investigator) when FDA has information that one or both of the following conditions exist (see 21 CFR 312.70, 511.1(c), and 812.119):
 - the investigator has repeatedly or deliberately failed to comply with applicable requirements for the conduct of clinical trials, or
 - the investigator has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report.
- In the event the Center, with OCC concurrence, determines that the clinical investigator's actions warrant the initiation of disqualification proceedings, the Center provides "written notice" of the matter(s) complained of and offers an opportunity for the investigator to explain the matter in writing or, at the option of the investigator, at an informal conference. The Center provides this written notice by way of a "Notice of Initiation of Disqualification Proceedings and Opportunity to Explain" (NIDPOE).
- If the clinical investigator does not respond to the NIDPOE or the response is inadequate, FDA issues a letter providing the investigator with a Notice of Opportunity for Hearing (NOOH) under 21 CFR Part 16, Regulatory Hearing before the Food and Drug Administration.
- If the clinical investigator responds to the NIDPOE in writing or at an informal conference and FDA accepts the investigator's explanation, FDA will discontinue the disqualification proceeding. FDA will notify the investigator in writing that FDA is discontinuing the disqualification proceeding.
- This SMG outlines the procedures to be followed after the ACRA has issued an NOOH.

5. RESPONSIBILITIES AND PROCEDURES

A. The Clinical Investigator's Response to NOOH

The NOOH directs the clinical investigator to respond to the Director, DE, who will send a copy of any response to the Office of the Chief Counsel (OCC), the Director, OGCP, and the Center's BIMO unit. Within 10 days of receiving the NOOH, the investigator may:

- fail to respond;
- decline the opportunity for a hearing and request in writing that the agency make a determination based on the available information; or
- request a hearing.

Although not specifically addressed in the regulations, an investigator may request additional time to respond to the NOOH, and the Center may decide to grant that request.

- 1. Fails to respond** – When a clinical investigator fails to respond within the time specified in the NOOH, the offer is deemed to have been refused and no hearing will be held (see 21 CFR 16.22(b)). If the investigator fails to respond by the deadline specified, the Director, DE, informs the Center and OGCP's Director and Project Manager.⁷

Within 60 days of DE's notification to the Center, based on available information, the Center BIMO unit prepares, in consultation with the Center's OCC counsel, a Decision Memorandum and Notice of Disqualification (see Attachments F and E). The Center should consult with the Project Manager in OGCP to determine the proper routing of documents following Center, Center OCC counsel, and ACRA clearance of the Decision Memorandum and Notice of Disqualification. Typically, the Center would route these documents to the Commissioner's counsel and the Commissioner or Commissioner's delegate for review and decision, with a copy to the Director, OGCP. (See section 5.C.1. of this document).

- 2. Declines a hearing** – If the clinical investigator declines a hearing and requests that FDA make a determination based on the available information, the Director, DE, informs the Center and OGCP's Director and Project Manager of the investigator's declination.

⁷ Delivery of the NOOH is confirmed when a signed mail receipt is received or a similar confirmation of delivery is documented. If, however, reasonable attempts to deliver the NOOH have been unsuccessful, the Center should promptly consult with Center OCC counsel regarding how to proceed.

Within 60 days of DE's notification to the Center, based on the available information, the Center BIMO unit prepares, in consultation with the Center's OCC counsel, a Decision Memorandum and Notice of Disqualification (see Attachments F and E). The Center should consult with the Project Manager in OGCP to determine the proper routing of documents following Center, Center OCC counsel, and ACRA clearance of the Decision Memorandum and Notice of Disqualification. Typically, the Center would route these documents to the Commissioner's counsel and the Commissioner or Commissioner's delegate for review and decision, with a copy to the Director, OGCP. (See section 5.C.1. of this document).

- 3. Requests additional time to respond** – If the clinical investigator requests additional time to respond, the Director, DE, will consult with the Center and Center's counsel for a determination of whether granting the request for additional time to respond to the NOOH is warranted, and will respond to the investigator within five days of receipt of the investigator's request. The Director, DE, will send a copy or otherwise notify the Center and OGCP's Director and Project Manager of the decision whether to allow additional time to respond to the NOOH.
- 4. Requests a hearing** – Upon receipt of a written request for a Part 16 hearing, the agency observes separation of functions (see Section 3. – Definitions, paragraph I., of this document). A request for a hearing must present specific facts showing that there is a genuine and substantial issue of fact that warrants a hearing. A hearing will not be granted on issues of policy or law (21 CFR 16.26(a)). The Commissioner will make the final decision on the matter as to whether a genuine and substantial issue of fact has been raised by the material submitted. If the Commissioner determines that a hearing is not justified, a Presiding Officer will not be designated.

If the clinical investigator requests a hearing:

- a. Generally, within one business day, the Director, DE, forwards a copy of the request to the Center, and OGCP's Director and Project Manager.
- b. Generally, within two business days, the Project Manager forwards the hearing request to OCC and requests that OCC designate counsel to represent the Commissioner consistent with separation of functions.

- c. Within seven days of receipt of the request for a hearing, OCC will provide to the Project Manager the name of the counsel to represent the Commissioner.
- d. Within 60 days of receipt of the request for a hearing, the Center, with the assistance of Center OCC counsel, may evaluate the hearing request to determine whether the investigator has raised any genuine and substantial issue of fact. If they conclude that no genuine and substantial issue of fact has been raised, the Center, within the 60 day time frame, may prepare and forward to the Project Manager, a Motion to Deny the Hearing and to Disqualify, with an accompanying memorandum. (See Attachment F).⁸ Please note that this Motion and memorandum should be cleared through the Center Director, Center OCC Counsel, and the ACRA within this 60 day time frame). Concurrent with the Center forwarding to the Project Manager the Motion to Deny the Hearing and to Disqualify and its accompanying memorandum, the Center OCC Counsel will send to the clinical investigator and the clinical investigator's counsel these documents consistent with separation of functions.

Generally, within three business days, the Project Manager will forward to the Commissioner and Commissioner's counsel the Center's Motion to Deny the Hearing and to Disqualify and its accompanying memorandum.

The Commissioner, with the assistance of counsel will review the Motion to Deny the Hearing and to Disqualify within 60 days of receipt and determine whether a hearing is warranted. If the Commissioner agrees that no hearing is warranted, and that the clinical investigator has repeatedly or deliberately violated the regulations or repeatedly or deliberately submitted false information, the Commissioner, with the assistance of counsel, will issue within 120 days of receipt a Commissioner's Decision and a Notice of Denial of Hearing and Disqualification letter (see Attachments G and C), disqualifying the investigator. The Commissioner's Decision will explain why the hearing was denied. (See section 5.C.2. of this document). The Commissioner will send to the Project Manager the Commissioner's Decision and Notice of Denial of Hearing and Disqualification letter. Within seven days of receipt, the Project Manager will forward the Notice of Denial of Hearing and Disqualification letter and Commissioner's Decision to the investigator and Center.

⁸ At the discretion of the Center, the Motion to Deny the Hearing and to Disqualify and the accompanying letter may be transmitted electronically.

If the Commissioner determines that the material submitted by the investigator raises a genuine and substantial issue of fact, the Commissioner will issue a decision letter granting the Part 16 hearing and send it to the Project Manager. Within three business days of receipt, the Project Manager will forward the decision letter to the investigator and Center, and will request designation of a Presiding Officer.⁹ The Project Manager will notify the Commissioner, Commissioner's counsel, investigator, investigator's counsel, Center and Center's OCC counsel about the Presiding Officer's name and contact information. The Presiding Officer may request the Project Manager to identify consultants (e.g., a medical officer or scientist) to provide to the Presiding Officer medical, scientific, or technical information.

- e. If the Center does not file a Motion to Deny the Hearing and to Disqualify, the investigator's request for hearing is deemed granted and the Project Manager will request designation of a Presiding Officer.

B. A Part 16 Hearing

- Federal rules of evidence do not apply to the Part 16 hearing (21 CFR 16.60(c)); and no specific format for the hearing is required of the parties.
- Any party to the hearing has the right at all times to be advised and accompanied by counsel (21 CFR 16.62).
- Off the record (or ex parte) communication by the Center or the clinical investigator with the Commissioner or Presiding Officer should be avoided (21 CFR 16.44(b)).
- Part 16 hearings are generally open to the public. However, the Commissioner may close all or part of the hearing on the Commissioner's own initiative or at the request of either party to prevent a clearly unwarranted disclosure of personal privacy, trade secret, or confidential commercial or financial information (see 21 CFR 16.60(a)).
- The Commissioner or Presiding Officer may, either voluntarily or at the request of a participant, waive, suspend, or modify any provisions in 21 CFR Part 16 applicable to the conduct of a public hearing by announcement at the hearing or by notice in advance of the hearing if

⁹ An Administrative Law Judge (ALJ) is authorized to act as Presiding Officer by the Commissioner. (21 CFR 16.42(a)).

no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with the law (21 CFR 10.19).

After a request for hearing is granted, the Project Manager arranges a telephone conference¹⁰ as soon as possible with the Presiding Officer, Center, and the clinical investigator, and their respective counsels, to establish a date for the hearing and a schedule for the submission of documents and materials relevant to the hearing, and to refine or narrow the issues to be resolved, if necessary.

- 1. Submission of Motion(s) for Summary Decision** – After the clinical investigator’s request for hearing is granted, the Center and investigator may file Motions for Summary Decision within the timeframe specified at the telephone conference, generally within 90 days.¹¹ Motions for Summary Decision argue that there is no “genuine and substantial issue of fact” regarding the issues in the proceeding (21 CFR 16.26(b)).

Motions for Summary Decision with attached memoranda:

- are informal in nature;
- may incorporate statements and documents by attaching them without the support of an affidavit; and
- have no set format, although the Presiding Officer may set a page limit to the Motions. This will be communicated during the telephone conference previously described.

NOTE: Center Motion. The Center will forward its Motion for Summary Decision to Center OCC counsel to review, and revise, if necessary. Center OCC counsel will then forward the document to the Presiding Officer, Project Manager, clinical investigator and clinical investigator’s counsel, if any.

Clinical Investigator’s Motion. The clinical investigator will be directed during the conference call with the Presiding Officer to forward a copy of his or her Motion for Summary Decision to the Presiding Officer, Project Manager, and Center’s OCC counsel.

- 2. Review of Motion(s) for Summary Decision** – Within 90 days of receipt, the Presiding Officer, with the assistance of counsel (if requested), will review the Motion(s) for Summary Decision and any

¹⁰ The process described in section 5.A.4.e of this document should be completed before the Project Manager arranges the telephone conference.

¹¹ The Presiding Officer will establish the time frames. Ninety days will include filing of motions by both parties and any opposition to such motions.

other matters officially noticed,¹² and issue a Summary Decision¹³ (see 21 CFR 16.26(b)) explaining whether there exists any genuine and substantial issue of fact to be decided at a hearing. Specifically, the Summary Decision explains whether the evidence presented shows that the clinical investigator has repeatedly or deliberately violated the regulations or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report.

- a. If the Presiding Officer agrees with the Center that there is no genuine and substantial issue of fact regarding whether the investigator has repeatedly or deliberately violated the regulations or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Presiding Officer issues a Summary Decision granting the Center's Motion in whole or in part, and recommending that the investigator be disqualified.

The Project Manager, within seven days of issuance of the Presiding Officer's Report, forwards the Report to the parties (see Attachment A).¹⁴ The parties have 30 days after receipt to review the Report and request review by the Commissioner (see 21 CFR 16.26(c)). Within the same 30 days after receipt, the parties may submit to the Project Manager¹⁵ comments on the Presiding Officer's Report.

The Project Manager forwards promptly to the Commissioner (or delegate) the request from a party for the Commissioner's review and/or a party's comments. The Commissioner, on the Commissioner's own initiative or at the request of either party, may review the Presiding Officer's Report and all related materials (21 CFR 16.26(c)). At the end of the 30 day period provided to the parties for comment, the Project Manager forwards to the Commissioner the Presiding Officer's Report, any request for review, and any comments received. Within 90 days of receipt of the Presiding Officer's Report and any comments received, the

¹² Official notice is a means of entering evidence into the administrative record and allows the Presiding Officer to take notice of commonly acknowledged facts, and any other matter peculiarly within the general knowledge of FDA as an expert agency. If official notice is taken of a material fact not appearing in the evidence of record, the parties will be afforded the opportunity to show the contrary.

¹³ The Summary Decision will be incorporated in a Presiding Officer's Report.

¹⁴ Note that the template letter (Attachment A) directs the parties to submit to the Project Manager any request for the Commissioner's review or any comments on the Presiding Officer's Report.

¹⁵ *Id.*

Commissioner will issue a decision on whether to disqualify the investigator. (See section 5.C.3.).

- b. If the Presiding Officer determines that the materials submitted by the investigator do raise an issue of fact as to whether the investigator violated the regulations and/or submitted false information to the sponsor or to FDA in any required report, the Presiding Officer issues a Summary Decision, denying the Center's Motion. A hearing will be scheduled.
- c. If the Presiding Officer determines that the materials submitted by the investigator and Center do not raise any issue of fact as to the investigator's actions, but the undisputed facts do not support the charges made by the Center, the Presiding Officer issues a Summary Decision recommending that the investigator not be disqualified. (See Attachment D).

The Project Manager, within seven days of issuance of the Presiding Officer's Report, forwards the Report to the parties (see Attachment A).¹⁶ The parties have 30 days after receipt to review the Report and request review by the Commissioner (see 21 CFR 16.26(c)). Within the same 30 days after receipt, the parties may submit to the Project Manager¹⁷ comments on the Presiding Officer's Report.

The Project Manager forwards promptly to the Commissioner (or delegate) the request from a party for the Commissioner's review and/or a party's comments. The Commissioner, on the Commissioner's own initiative or at the request of either party, may review the Presiding Officer's Report and all related materials (21 CFR 16.26(c)). At the end of the 30 day period provided to the parties for comment, the Project Manager forwards to the Commissioner the Presiding Officer's Report, any request for review, and any comments received. Within 90 days of receipt of the Presiding Officer's Report and any comments received, the Commissioner will issue a decision on whether to disqualify the investigator. (See section 5.C.3.).

- d. Scheduling of the hearing, when indicated – If after reviewing the Motions, the Presiding Officer determines that a hearing is necessary, the Presiding Officer will send a letter to all parties. Within 10 days of the Presiding Officer issuing the letter, the Project

¹⁶ *Id.*

¹⁷ *Id.*

Manager, with the Presiding Officer, notifies the Center, the investigator, and their respective attorneys to arrange a date (preferably within 30 days), time, and location for the hearing. If the parties cannot agree, the Presiding Officer will designate a reasonable time and location (21 CFR 16.22(c)).

3. **Hearing Process** – The following steps apply to the hearing process.
 - a. **Prior to hearing** – At least one day before the hearing, if feasible, the Center and the clinical investigator will provide each other with written notice of any published or written information to be presented or relied on at the hearing, if feasible. A copy will also be provided in advance if the other party could not reasonably be expected to have or be able to obtain a copy (21 CFR 16.24(g)).
 - b. **Hearing Transcript** – It is the responsibility of the Center to arrange for a transcript to be made of the hearing. The Center should provide the Project Manager with the name of the firm (and individual, if available) who will be preparing the transcript. Costs associated with transcription services will be borne by the Center. (21 CFR 16.60(d)).
 - c. **Witnesses** – It is the responsibility of the Center to identify and contact any witnesses to be used by the Center during the hearing (usually FDA employees). At the hearing, the witnesses will provide oral testimony and submit documentary evidence to the Presiding Officer.
 - d. **Conduct of the Hearing** – The oral portion of the hearing consists primarily of a full and complete statement of the action, direct and reasonable cross-examination (see 21 CFR 16.60(b)).
 - e. **Presiding Officer Report** – Within 90 days after the conclusion of the hearing, the Presiding Officer prepares a Report of the hearing. All written material presented at the hearing will be attached to the Report (21 CFR 16.60(e)). The Report will include a finding on the credibility of the witnesses (other than expert witnesses) whenever credibility is a material issue in the proceeding, and must include a recommended decision, with a statement of reasons, unless the Commissioner directs otherwise (21 CFR 16.60(f)). (See section 5.C.4.).

Within seven days, the Project Manager sends the Report to the parties (see Attachment B). Whenever time permits, the parties to the hearing will be given the opportunity to review and comment on the Report (21 CFR 16.60(e)).

C. Commissioner's Decision

The Commissioner will issue a decision regarding the eligibility of the clinical investigator to receive test articles and to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA (21 CFR 312.70(b), 511.1(c)(2), or 812.119(b)), under one of the following four pathways:

1. Commissioner's Decision When the Clinical Investigator Does Not Request a Hearing

If the clinical investigator fails to respond to the NOOH or declines the opportunity for a hearing, the Commissioner will review the Decision Memorandum submitted by the Center (see Attachment F) and issue a decision within 90 days. The Commissioner may accept, in whole or in part, the findings of the Center regarding the violations alleged to be committed by the investigator. If the Commissioner adopts the Center's recommendation for disqualification of the investigator, the Commissioner will sign the Decision Memorandum and the Notice of Disqualification (see Attachment E) prepared by the Center (see section 5.A.1.) and forward these documents to the Project Manager. The Decision Memorandum must state the reasons for the Commissioner's administrative action and the basis in the record (21 CFR 16.95(b)(2)).

Within seven days, the Project Manager:

- (1) Issues the signed Notice of Disqualification to the clinical investigator and his/her counsel by certified mail (return receipt) or other documented method of transmission;
- (2) Notifies the Center when receipt of the Notice of Disqualification by the clinical investigator and his/her counsel is confirmed;¹⁸ and
- (3) Provides a copy of the Notice of Disqualification to the Center and Center's counsel.

As soon as possible after the confirmed delivery,¹⁹ the Center issues letters to the sponsor(s)²⁰ and reviewing Institutional Review Board(s)

¹⁸ If delivery cannot be confirmed, the Center issues the letters to the sponsor(s) and IRB(s) after reasonable attempts are made to contact the clinical investigator.

¹⁹ *Id.*

(IRB(s)) of any investigation(s) in which the investigator has been named as a participant.^{21 22} The letters should explain that the investigator is disqualified and provide a statement of the basis for that determination, such as a copy of the Notice of Disqualification. The letter should ask the sponsor(s) to examine all investigational²³ and marketing²⁴ applications containing data reported by the disqualified investigator to determine whether the investigator has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval of any marketing application.

Within 14 days of confirmed delivery,²⁵ the Center will:

- (1) Provide copies of the Notice of Disqualification to other appropriate FDA offices;
- (2) Forward the Notice of Disqualification to the Center's FOI program for redaction; and
- (3) Forward information about the clinical investigator's disqualification to the Director, DE, so that the investigator's name can be included in the list of disqualified clinical investigators on FDA's webpage [<http://www.fda.gov/DisqualificationProceedings>].

If the Commissioner does not adopt the Center's recommendation to disqualify, the Commissioner, with the assistance of counsel, will prepare, and forward to the Project Manager, a letter to notify the investigator.²⁶ Within seven days, the Project Manager will send the letter to the investigator by certified mail (return receipt) or other

²⁰ The Center should notify only the current sponsor or, if an applicable submission has been withdrawn, the sponsor of the withdrawn submission. If there has been a transfer to a new sponsor, please consult with the Office of the Chief Counsel concerning sponsor notification.

²¹ FDA Information Disclosure Manual, Section IV, Sharing Non-Public Information with Sponsors and Institutional Review Boards.

²² Privacy Act System of Records 09-10-0010 for the "Bioresearch Monitoring Information System, HHS/FDA."

²³ Investigational New Drug Application, Investigational Device Exemption, and Notice of Claimed Investigational Exemption for a New Animal Drug.

²⁴ Biologics License Application, New Drug Application, Premarket Approval Application, Product Development Protocol, Humanitarian Device Exemption Application, Premarket Notification (510(k)) Submission, New Animal Drug Application.

²⁵ If delivery cannot be confirmed, the Center issues the letters to the sponsor(s) and IRB(s) after reasonable attempts are made to contact the clinical investigator.

²⁶ We recommend that the Commissioner issue a memo to the file, outlining the basis for the determination.

documented method of transmission. A copy of the letter (and memo, if any) is sent to the Center.

Within 14 days of confirmed delivery, the Center will:

- (1) Provide copies of the letter to other appropriate FDA offices; and
- (2) Forward the letter to the Center's FOI program for redaction and posting on FDA's Clinical Investigators – Disqualification Proceedings webpage, as appropriate. [<http://www.fda.gov/DisqualificationProceedings>]

2. Notice When the Clinical Investigator's Request for a Hearing is Denied

If the Commissioner grants the Center's Motion to Deny the Hearing and to Disqualify (see section 5.A.4.d.), the Commissioner, with the assistance of counsel, will issue a Notice of Denial of Hearing and Disqualification (see Attachment C) and forward the Notice to the Project Manager.

Within seven days, the Project Manager:

- (1) Issues the signed Notice of Denial of Hearing and Disqualification to the clinical investigator and his/her counsel by certified mail (return receipt) or other documented method of transmission;
- (2) Notifies the Center when receipt of the Notice of Denial of Hearing and Disqualification by the clinical investigator and his/her counsel is confirmed;²⁷ and
- (3) Provides a copy of the Notice of Denial of Hearing and Disqualification to the Center and Center's counsel.

As soon as possible after confirmed delivery,²⁸ the Center issues letters to the sponsor(s) and reviewing IRB(s) of any investigation(s) in which the investigator has been named as a participant.^{29 30} The letters should explain that the investigator is disqualified and will

²⁷ If delivery cannot be confirmed, the Center issues the letters to the sponsor(s) and IRB(s) after reasonable attempts are made to contact the clinical investigator.

²⁸ *Id.*

²⁹ FDA Information Disclosure Manual, Section IV, Sharing Non-Public Information with Sponsors and Institutional Review Boards.

³⁰ Privacy Act System of Records 09-10-0010 for the "Bioresearch Monitoring Information System, HHS/FDA."

provide a statement of the basis for that determination, such as a copy of the Notice of Denial of Hearing and Disqualification. The letter should ask the sponsor(s) to examine all investigational³¹ and marketing³² applications containing data reported by the disqualified investigator to determine whether the investigator has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval of any marketing application.

Within 14 days of confirmed delivery,³³ the Center will:

- (1) Provide copies of the Notice of Denial of Hearing and Disqualification to other appropriate FDA offices;
- (2) Forward the Notice of Denial of Hearing and Disqualification to the Center's FOI program for redaction and posting on FDA's Clinical Investigators – Disqualification Proceedings webpage, as appropriate; and
- (3) Forward information about the investigator's disqualification to the Director, DE, so that the investigator's name can be included in the list of disqualified clinical investigators on FDA's website [<http://www.fda.gov/DisqualificationProceedings>].

3. Commissioner's Decision After the Presiding Officer's Summary Decision (Included in the Presiding Officer's Report)

The Commissioner may review any Summary Decision issued. Either party may request this review or the Commissioner may review the Summary Decision on the Commissioner's own initiative (21 CFR 16.26(c)). The Presiding Officer's Summary Decision is forwarded to the Commissioner, who will issue, within 90 days, a written Commissioner's Decision³⁴ (see Attachments G and H) either disqualifying the investigator from being eligible to receive investigational test articles and to conduct any clinical investigation that supports an application for a research or marketing permit for products

³¹ Investigational New Drug Application, Investigational Device Exemption, and Notice of Claimed Investigational Exemption for a New Animal Drug.

³² Biologics License Application, New Drug Application, Premarket Approval Application, Product Development Protocol, Humanitarian Device Exemption Application, Premarket Notification (510(k)) Submission, New Animal Drug Application.

³³ If delivery cannot be confirmed, the Center issues the letters to the sponsor(s) and IRB(s) after reasonable attempts are made to contact the clinical investigator.

³⁴ The Commissioner's Decision need not repeat all of the underlying arguments and basis contained in the Presiding Officer's Report; it may be as simple as a one page letter stating that the Presiding Officer's Decision has been adopted by the Commissioner.

regulated by FDA, or determining that the investigator did not repeatedly or deliberately fail to comply with the regulations or repeatedly or deliberately submit to FDA or to the sponsor false information in any required report. The Commissioner's Decision must state the reasons for the Commissioner's administrative action and the basis in the record (21 CFR 16.95(b)(2)).

a. Commissioner Determines that the Clinical Investigator Should Be Disqualified

If the Commissioner determines that the investigator should be disqualified, that is, the investigator has repeatedly or deliberately failed to comply with the requirements in the regulations, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, within the above 90 days, the Commissioner, with the assistance of counsel, will issue a Commissioner's Decision (see Attachment G). The Commissioner, with the assistance of counsel, will also prepare a Notice of Disqualification (see Attachment E) to inform the investigator that he or she has been disqualified and forward a copy to the Project Manager. The notification will include a statement of the basis for such determination (21 CFR 312.70(b), 511.1(c)(2), and 812.119(b)).

Although the Commissioner may find that the investigator did not violate all the regulations cited by the Center in the NOOH, the investigator may still be disqualified if the investigator has repeatedly or deliberately violated any regulations cited, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report.

Within seven days, the Project Manager:

- (1) Issues the signed Notice of Disqualification and a copy of the Commissioner's Decision to the clinical investigator and the investigator's counsel by certified mail (return receipt) or other documented method of transmission;
- (2) Notifies the Center when receipt of the Notice of Disqualification by the clinical investigator and the investigator's counsel is confirmed; and
- (3) Provides a copy of the Notice of Disqualification and Commissioner's Decision to the Center and Center's counsel.

As soon as possible after confirmed delivery,³⁵ the Center issues letters to the sponsor(s) and reviewing IRB(s) of any investigation(s) in which the investigator has been named as a participant.^{36 37} The letters should explain that the investigator is disqualified and will provide a statement of the basis for that determination, such as a copy of the Notice of Disqualification. The letter should ask the sponsors to examine all investigational²³ and marketing²⁴ applications submitted containing data reported by the disqualified investigator, to determine and advise the Center whether the investigator has submitted unreliable data that are essential to the continuation of any investigation or essential to the approval of any marketing application.

Within 14 days of confirmed delivery, the Center will:

- (1) Provide copies of the Notice of Disqualification to other appropriate FDA offices;
- (2) Forward the Notice of Disqualification and Commissioner's Decision to the Center's FOI program for redaction and posting on FDA's Clinical Investigators – Disqualification Proceedings webpage, as appropriate; and
- (3) Forward information about the investigator's disqualification to the Director, DE, so that the investigator's name can be included in the list of disqualified clinical investigators on FDA's webpage [<http://www.fda.gov/DisqualificationProceedings>].

b. Commissioner Determines that the Clinical Investigator Should Not Be Disqualified

If the Commissioner does not adopt the Center's recommendation to disqualify, the Commissioner, with the assistance of counsel, will prepare, and forward to the Project Manager, a Commissioner's Decision explaining the decision.³⁸ (See Attachments D and G). Within seven days of receipt of the Commissioner's Decision, the Project Manager will send a copy of the Commissioner's Decision to the investigator by certified mail (return receipt) or other

³⁵ If delivery cannot be confirmed, the Center issues the letters to the sponsor(s) and IRB(s) after reasonable attempts are made to contact the clinical investigator.

³⁶ FDA Information Disclosure Manual, Section IV, Sharing Non-Public Information with Sponsors and Institutional Review Boards.

³⁷ Privacy Act System of Records 09-10-0010 for the "Bioresearch Monitoring Information System, HHS/FDA."

³⁸ NOTE: The regulations do not grant the Center the option of requesting a hearing on those issues not summarily decided; the regulations only provide the clinical investigator with the option of requesting a hearing.

documented method of transmission. A copy of the Commissioner's Decision is sent to the Center.

Within 14 days of confirmed delivery,³⁹ the Center will:

- (1) Provide copies of the Commissioner's Decision to other appropriate FDA offices; and
- (2) Forward the Commissioner's Decision to the Center's FOI program for redaction and posting on FDA's Clinical Investigators – Disqualification Proceedings webpage [<http://www.fda.gov/DisqualificationProceedings>].

4. Commissioner's Decision After the Presiding Officer's Report on the Regulatory Hearing

The Presiding Officer's Report on the Part 16 Hearing, including any attachments and comments, is forwarded to the Commissioner. With the assistance of counsel, the Commissioner issues a written Commissioner's Decision within 90 days of receipt.⁴⁰ (See Attachments G and H). The Commissioner's Decision shall state the reasons for the Commissioner's administrative action and the basis in the record (21 CFR 16.95(b)(2)). The Commissioner's Decision may be in the form of a report (see Attachment G) or letter (see Attachment H).

a. Commissioner Determines the Clinical Investigator Should Be Disqualified

If, after reviewing the administrative record, including the Presiding Officer's Report, the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the requirements in the regulations, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Commissioner with the assistance of counsel will prepare a Commissioner's Decision (see Attachment G) and a Notice of Disqualification (see Attachment C) and send those documents to the Project Manager.

Within seven days, the Project Manager:

³⁹ If delivery cannot be confirmed, the Center issues the letters to the sponsor(s) and IRB(s) after reasonable attempts are made to contact the clinical investigator.

⁴⁰ The Commissioner's Decision need not repeat all of the underlying arguments and basis contained in the Presiding Officer's Report; it may be as simple as a one page letter stating that the Presiding Officer's Decision has been adopted by the Commissioner.

- (1) Issues the signed Notice of Disqualification and a copy of the Commissioner's Decision to the clinical investigator and the investigator's counsel by certified mail (return receipt) or other documented method of transmission;
- (2) Notifies the Center when receipt of the Notice of Disqualification by the clinical investigator and the investigator's counsel is confirmed;⁴¹ and
- (3) Provides a copy of the Notice of Disqualification and Commissioner's Decision to the Center.

As soon as possible after confirmed delivery,¹⁹ the Center issues letters to the sponsor(s) and reviewing IRB(s) of any investigation in which the investigator has been named as a participant.^{21,22} The letters should explain that the investigator is disqualified and will provide a statement of the basis for that determination, such as a copy of the Notice of Disqualification. The letter should ask the sponsor(s) to examine all investigational²³ and marketing²⁴ applications submitted containing data reported by the disqualified investigator to determine whether the investigator has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval of any marketing application.

Within 14 days of confirmed delivery,⁴² the Center will:

- (1) Provide copies of the Notice of Disqualification to other appropriate FDA offices;
- (2) Forward the Notice of Disqualification and the Commissioner's Decision to the Center's FOI program for redaction and posting on FDA's Clinical Investigators – Disqualification Proceedings webpage; and
- (3) Forward information about the investigator's disqualification to the Director, DE, so that the investigator's name can be included in the list of disqualified clinical investigators on FDA's webpage [<http://www.fda.gov/DisqualificationProceedings>].

b. Commissioner Determines the Clinical Investigator Should Not Be Disqualified

⁴¹ If delivery cannot be confirmed, the Center issues the letters to the sponsor(s) and IRB(s) after reasonable attempts are made to contact the clinical investigator.

⁴² *Id.*

If after reviewing the administrative record, including the Presiding Officer's Report, the Commissioner determines not to disqualify, within 90 days, the Commissioner with the assistance of counsel will prepare a Commissioner's Decision and/or letter. (See Attachments G and H). Within seven days of the Commissioner's Decision, the Project Manager will send the letter and/or Commissioner's Decision to the clinical investigator and the investigator's counsel by certified mail (return receipt) or other documented method of transmission. A copy of the letter is sent to the Center.

Within 14 days of confirmed delivery,⁴³ the Center will:

- (1) Provide copies of the Commissioner's Decision and/or letter to other appropriate FDA offices; and
- (2) Forward the Commissioner's Decision and/or letter to the Center's FOI program for redaction and posting, as appropriate, on FDA's Clinical Investigators – Disqualification Proceedings webpage. [<http://www.fda.gov/DisqualificationProceedings>].

D. Administrative Record and Posting of Documents

Copies of all documents are sent to the OGCP Project Manager for purposes of recordkeeping.⁴⁴ The Center is responsible for forwarding the documents to the Center's FOI contact and DE, so that as appropriate, all applicable documents may be posted on the agency website (after redaction), e.g., NIDPOE, NOOH, Notice of Disqualification, Notice of Denial of Hearing and Disqualification, the Presiding Officer's Report, and Commissioner's Decision.

6. EFFECTIVE DATE.

This FDA Staff Manual Guide is effective as of August 25, 2014.

⁴³ *Id.*

⁴⁴ See SMG 7711.1 – Maintaining and Controlling Part 16 Regulatory Hearing Administrative Records for Investigator Disqualification Matters (<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM246092.pdf>).

7. Document History -- SMG 7711, Disqualification of a Clinical Investigator: The Hearing Process

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/20/2008	n/a	Kathleen Pfaender, Senior Health Policy Analyst, Good Clinical Practice Program (GCPP), Office of the Commissioner (OC)	Joanne R. Less, Ph.D., Director, Good Clinical Practice Program (HF-34)
Change	10/09/2008	Footnote 6; Section 5,B,2,c	Kathleen Pfaender, Senior Health Policy Analyst, GCPP, OC	Kathleen Pfaender, Senior Health Policy Analyst, GCPP, OC
Change	06/12/2009	Hyperlinks in Section 5.C.1.; 5.C.2.; 5.C.3.a.,b.; 5.C.4.a.,b.	Kathleen Swisher Pfaender, Senior Health Policy Analyst, GCPP, OC	Kathleen Swisher Pfaender, Senior Health Policy Analyst, GCPP, OC
Revision	10/16/2009	N/a	Kathleen Pfaender, Senior Health Policy Analyst, Office of Good Clinical Practice (OGCP), OC	Joanne R. Less, Ph.D., Director, OGCP, and Kathleen Pfaender, Senior Health Policy Analyst, OGCP, OC
Change	12/22/2009	Good Clinical Practice Program to Office of Good Clinical Practice, Section 5.A.; correction to text in Attachment D	Kathleen Pfaender, Senior Health Policy Analyst, OGCP, OC	Kathleen Pfaender, Senior Health Policy Analyst, OGCP, OC
Change	08/18/2010	Attachment C: delete "and"; insert "or"	Kathleen Pfaender, Senior Health Policy Analyst, OGCP, OC	Kathleen Pfaender, Senior Health Policy Analyst, OGCP, OC
Revision	08/10/2011	N/a	Kathleen Pfaender, Senior Health Policy Analyst, OGCP, OC	Joanne R. Less, Ph.D., Director, OGCP
Change	11/19/2012	Updated URL's to new CI Disqualification Proceedings webpage; updated for FDA reorganizations; corrected typos – footnote 8 & section 5.C.2, 1st paragraph	Kathleen Pfaender, OGCP, OC	Kathleen Pfaender, OGCP, OC
Change	05/14/2014	Throughout – updates for CI disqualification final rule & DOAs	Kathleen Pfaender, OGCP, OSMP	Joanne R. Less, OGCP, OSMP
Change	07/09/2014	Throughout – corrected typos	Kathleen Pfaender, OGCP, OSMP	Kathleen Pfaender, OGCP, OSMP

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Revision	08/25/2014	N/a	OC/OMPT/ OSMP/OGCP	Joanne R. Less, Director, OC/OGCP

**[Investigator/Investigator's Counsel & Center's Counsel Notification of
Presiding Officer Report under 21 CFR 16.26(b)]**

[DATE]

By Certified Mail [or other documented method of transmission] - **Return
Receipt Requested** [or] **Hand Delivered**

[INVESTIGATOR] [INVESTIGATOR'S COUNSEL]
[ADDRESS]

[or]

[CENTER OCC COUNSEL]
[ADDRESS]

Regarding: In the Matter of [INVESTIGATOR]

Dear [INVESTIGATOR] [and/or COUNSEL] [or] [CENTER OCC COUNSEL]:

Enclosed you will find the "Report of the Presiding Officer," issued on [DATE], concerning the above referenced matter. The Presiding Officer issued this Report under Title 21, Code of Federal Regulations (21 CFR), §16.26(b). The Report is provided to you as a party to the matter, or as counsel to a party.

In accordance with 21 CFR §16.26(c), you may request that the Commissioner or his or her delegate review the enclosed Report. Within thirty (30) days of the date you receive the Report, submit any request for review and any comments you may have on the Report to the Project Manager, [NAME, ADDRESS, FAX NUMBER OF PROJECT MANAGER].

The Commissioner (or delegate) will consider as part of the administrative record any comments you submit (see 21 CFR §16.80(a)). The Commissioner (or delegate) will issue a written decision on the basis of the administrative record pursuant to 21 CFR §16.95(a).

Sincerely,

[PROJECT MANAGER SIGNATURE]

[NAME/TITLE]

Enclosure

bcc:

*[To blind copy electronically, send to the relevant party at
firstname.lastname@fda.hhs.gov; for hardcopy distribution at the White Oak
(WO) campus, include the building and room numbers]*

OCC; WO31/WO32

DFOI; HFI-30

OGCP; WO32-5129

ORA, Division of Enforcement (DE), Office of Enforcement and Import
Operations (OEIO), Office of Operations (OO); WO32

*[Relevant District Office – District Personnel, including the District Director;
Director, Investigations Branch; and the District Investigator(s)]*

CDER, DSI; WO51

CBER, BIMO Group; HFM-664

CVM, BIMO Group; HFV-234

CDRH, BIMO Group; WO66, BIMO@cdrh.fda.gov

CFSAN, BIMO Group; HFS-205

CFSAN, OCD; HFS-265

[Originating Center – Center files and distribution]

**[Investigator/Investigator's Counsel & Center's Counsel Notification
after issuance of Presiding Officer's written report of a Part 16
hearing under 21 CFR 16.60(e)]**

[DATE]

**By Certified Mail [or other documented method of transmission] - Return
Receipt Requested [or] Hand Delivered**

[INVESTIGATOR] [INVESTIGATOR'S COUNSEL]
[ADDRESS]

[or]

[CENTER OCC COUNSEL]
[ADDRESS]

Regarding: Part 16 Regulatory Hearing In the Matter of [INVESTIGATOR]

Dear [INVESTIGATOR] [and/or COUNSEL] [or] [CENTER OCC COUNSEL]:

Enclosed you will find the Presiding Officer's written report dated [DATE], of the hearing referenced above held on [DATE OF HEARING]. The Presiding Officer prepared this report under Title 21, Code of Federal Regulations (21 CFR), §16.60(e). The report is provided to you as a party to the Part 16 regulatory hearing, or as counsel to a party.

In accordance with 21 CFR §16.60(e), you may review and comment on the Presiding Officer's report of the hearing. Within thirty (30) days of the date you receive the report, submit any comments you may have on the report to the Project Manager, [NAME, ADDRESS, FAX NUMBER OF PROJECT MANAGER].

The Commissioner (or delegate) will consider as part of the administrative record any comments you submit (see 21 CFR §16.80(a)). The Commissioner (or delegate) will issue a written decision on the basis of the administrative record pursuant to 21 CFR §16.95(a).

Sincerely,

[PROJECT MANAGER SIGNATURE]

[NAME/TITLE]

Enclosure

bcc:

*[To blind copy electronically, send to the relevant party at
firstname.lastname@fda.hhs.gov; for hardcopy distribution at the White Oak
(WO) campus, include the building and room numbers]*

OCC; WO31/WO32

DFOI; HFI-30

OGCP; WO32-5129

ORA, Division of Enforcement (DE), Office of Enforcement and Import
Operations (OEIO), Office of Operations (OO); WO32

ORA, OE, DE; WO32

ORA, DCP, OE; HFC-230

*[Relevant District Office – District Personnel, including the District Director;
Director, Investigations Branch; and the District Investigator(s)]*

CDER, OSI; WO51

CBER, BIMO Group; HFM-664

CVM, BIMO Group; HFV-234

CDRH, BIMO Group; WO66, BIMO@cdrh.fda.gov

CFSAN, BIMO Group; HFS-205

CFSAN, OCD; HFS-265

[Originating Center – Center files and distribution]

[Date]

By Certified Mail [or other documented method of transmission] - Return Receipt Requested

[CI Name]
[Address]

[Name of Counsel]
[Address]

Notice of Denial of Hearing and Disqualification

Dear Dr. [INVESTIGATOR] [and/or COUNSEL]:

I have reviewed the administrative record of the regulatory disqualification proceeding involving Dr. [CI Name]. On the basis of all information available to FDA, I have determined that there is no genuine and substantial issue of fact with regard to whether Dr. [CI Name] repeatedly or deliberately failed to comply with pertinent regulations governing the conduct of clinical investigators and the use of investigational [new drugs or new animal drugs or devices] or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report.

[If signed by the Commissioner's delegate, add and edit this paragraph accordingly: Under the authority delegated to me by the Commissioner of Food and Drugs, I am issuing this Commissioner's Decision.] I am therefore granting [Center's] Request for Hearing Denial and, in accordance with 21 CFR Part 16 and § [312.70(b) or 511.1(c)(2) or 812.119(b)], I have determined that Dr. [CI Name] is no longer eligible to receive test articles under 21 CFR Part [312, 511, or 812]. As a result of my determination, Dr. [CI Name] is no longer eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

Dr. [CI Name] may seek to have his eligibility reinstated, pursuant to 21 CFR [312.70(f), 511.1(c)(6), or 812.119(f)] upon presentation of 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 FDA regulations.

Sincerely,

Commissioner of Food and Drugs [or delegate]

Enclosure

bcc:

*[To blind copy electronically, send to the relevant party at
firstname.lastname@fda.hhs.gov; for hardcopy distribution at the White Oak
(WO) campus, include the building and room numbers]*

OCC; WO31/WO32

DFOI; HFI-30

OGCP; WO32-5129

ORA, Division of Enforcement (DE), Office of Enforcement and Import
Operations (OEIO), Office of Operations (OO); WO32

*[Relevant District Office – District Personnel, including the District Director;
Director, Investigations Branch; and the District Investigator(s)]*

CDER, OSI; WO51

CBER, BIMO Group; HFM-664

CVM, BIMO Group; HFV-234

CDRH, BIMO Group; WO66, BIMO@cdrh.fda.gov

CFSAN, BIMO Group; HFS-205

CFSAN, OCD; HFS-265

[Originating Center – Center files and distribution]

[Date]

By Certified Mail [or other documented method of transmission] - **Return Receipt Requested**

[CI Name]
[Address]

[Name of Counsel]
[Address]

Notice of Continuation of Eligibility to Receive Test Articles

Dear Dr. [INVESTIGATOR] [and/or COUNSEL]:

I have reviewed the administrative record of the regulatory disqualification proceeding involving Dr. [CI Name]. On the basis of all information available to FDA, I have determined that Dr. [CI Name] did not repeatedly or deliberately violate 21 CFR Part [312, 511, or 812] in connection with [an investigational new drug study] [an investigational new animal drug study] [an investigational device study] of [name of product]; or, did not repeatedly or deliberately submit to FDA or the sponsor false information in any required report. I am therefore granting Dr. [CI Name]'s Motion and, consistent with 21 CFR [312.70 or 511.1(c) or 812.119], I have determined that Dr. [CI Name] continues to be eligible to receive investigational [product]. [If signed by the Commissioner's delegate, insert: Under the authority delegated to me by the Commissioner of Food and Drugs, I am issuing this Commissioner's Decision in which I have determined that Dr. [CI Name] continues to be eligible to receive investigational [product]]. [Add if enclosing a Commissioner's decision: The reasons for this determination are set forth in the enclosed decision.]

Sincerely,

[Signature]

[Name]
Commissioner of Food and Drugs [or delegate]

Enclosure

bcc:

*[To blind copy electronically, send to the relevant party at
firstname.lastname@fda.hhs.gov; for hardcopy distribution at the White Oak
(WO) campus, include the building and room numbers]*

OCC; WO31/WO32

DFOI; HFI-30

OGCP; WO32-5129

ORA, Division of Enforcement (DE), Office of Enforcement and Import
Operations (OEIO), Office of Operations (OO); WO32

*[Relevant District Office – District Personnel, including the District Director;
Director, Investigations Branch; and the District Investigator(s)]*

CDER, OSI; WO51

CBER, BIMO Group; HFM-664

CVM, BIMO Group; HFV-234

CDRH, BIMO Group; WO66, BIMO@cdrh.fda.gov

CFSAN, BIMO Group; HFS-205

CFSAN, OCD; HFS-265

[Originating Center – Center files and distribution]

[Date]

By Certified Mail [or other documented method of transmission] - Return Receipt Requested

[CI Name]
[Address]

[Name of Counsel]
[Address]

Notice of Disqualification

Dear Dr. [INVESTIGATOR] [and/or COUNSEL]:

I have reviewed the administrative record of the regulatory disqualification proceeding involving Dr. [CI Name]. On the basis of all information available to FDA, I have determined that there is no genuine and substantial issue of fact with regard to whether Dr. [CI Name] repeatedly or deliberately failed to comply with pertinent regulations governing the conduct of clinical investigators and the use of investigational [new drugs or new animal drugs or devices] or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report.

[If signed by the Commissioner's delegate, add and edit this paragraph accordingly: Under the authority delegated to me by the Commissioner of Food and Drugs, I am issuing this Commissioner's decision.] In accordance with 21 CFR Part 16 and § [312.70(b) or 511.1(c)(2) or 812.119(b)], I have determined that Dr. [CI Name] is no longer eligible to receive test articles under 21 CFR Part [312, 511, or 812]. As a result of my determination, Dr. [CI Name] is no longer eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

Dr. [CI Name] may seek to have [his or her] eligibility reinstated pursuant to [312.70(f), 511.1(c)(6), or 812.119(f)] upon presentation of 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 FDA regulations.

Sincerely,

[Signature]
Name
Commissioner of Food and Drugs [or delegate]

Enclosure

bcc:

*[To blind copy electronically, send to the relevant party at
firstname.lastname@fda.hhs.gov; for hardcopy distribution at the White Oak
(WO) campus, include the building and room numbers]*

OCC; WO31/WO32

DFOI; HFI-30

OGCP; WO32-5129

ORA, Division of Enforcement (DE), Office of Enforcement and Import
Operations (OEIO), Office of Operations (OO); WO32

*[Relevant District Office – District Personnel, including the District Director;
Director, Investigations Branch; and the District Investigator(s)]*

CDER, OSI; WO51

CBER, BIMO Group; HFM-664

CVM, BIMO Group; HFV-234

CDRH, BIMO Group; WO66, BIMO@cdrh.fda.gov

CFSAN, BIMO Group; HFS-205

CFSAN, OCD; HFS-265

[Originating Center – Center files and distribution]

Routing/Clearance, Center Decision Memorandum

Date:

To: Commissioner of Food and Drugs [or delegate]

From: Director (Office, Mailing Code)

Through: Director (Center, Mailing Code)

[Name]/Center Counsel, Office of the General Counsel, GCF-1

Associate Commissioner for Regulatory Affairs, HFC-1

[Name]/Commissioner's Counsel, Office of the General Counsel, GCF-1

Subject: Proposed [Notice of Denial of Hearing and] Disqualification of [Name], [Title], [City, State] – ACTION

ACTION REQUESTED

I request your decision, under 21 CFR Parts 16 and [312, 511, or 812], regarding our recommendation (below) to disqualify [Name]. If you agree with the recommendation, I request your signature on the last page of this recommendation, and on the attached "Notice of [Denial of Hearing and] Disqualification" (Attachment 1), to be issued to Dr. [Name].

BACKGROUND

[Provide summary of matter.]

CONCLUSION

DECISION

Pursuant to 21 CFR Parts 16 and [312, 511, 812], the Food and Drug Administration hereby [denies the hearing request and] disqualifies [Name, Title] from receiving test articles under 21 CFR Part [312, 511, or 812]. Also, pursuant to § [312.70(b), 511.1(c)(2), or 812.119(b)] [Name] is no longer eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

Approved _____

Disapproved _____

Signature
Name
Title

Date

ATTACHMENTS

Notice of [Denial of Hearing and] Disqualification

[Supporting documentation, as appropriate, e.g., NIDPOE, evidence of receipt of NIDPOE, response to NIDPOE, transcript of informal hearing (if any), NOOH, evidence of response to NOOH, hearing transcript, relevant correspondence, plea agreement (if any)]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

REGULATORY [HEARING] or [PROCEEDING] ON THE PROPOSAL TO
DISQUALIFY

Dr. [NAME]

FROM RECEIVING INVESTIGATIONAL TEST ARTICLES

COMMISSIONER'S DECISION

[Brief summary of case, with decision: In this proceeding, the [Center] proposes that pursuant to 21 CFR Parts 16 and [312, 511, or 812], Dr. [Name] be disqualified from receiving test articles under 21 CFR Part [312, 511, or 812] and, therefore, be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA. [Center] has moved to deny Dr. [Name]'s request for a hearing under 21 CFR 16.26(a), and to disqualify him/her under 21 CFR [312.70, 511.1(c), or 812.119].

[Based upon my review of the parties' submissions, I find that there is no genuine and substantial issue of fact with regard to whether Dr. [Name] repeatedly or deliberately violated 21 CFR Part [##] or submitted to FDA or the sponsor false information in any required report. I am therefore granting [Center's] motion to deny Dr. [Name's] request for a hearing and to disqualify Dr. [Name] from receiving test articles. Also, pursuant to § [312.70(b), 511.1(c)(2), or 812.119(b)] Dr. [Name] is no longer eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.] [Under the authority delegated to me by the Commissioner of Food and Drugs, I am issuing this Commissioner's Decision denying Dr. [Name]'s request for a hearing and disqualifying Dr. [Name] from eligibility to receive test articles under 21 CFR Part [312, 511, or 812]. Also, pursuant to § [312.70(b), 511.1(c)(2), or 812.119(b)] Dr. [Name] is no longer eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.]

OR

[Based upon my review of the parties' submissions, I find that there is a genuine and substantial issue of fact with regard to whether Dr. [Name] repeatedly or deliberately violated 21 CFR Part [##] or submitted to FDA or the sponsor false information in any required report. I am therefore granting Dr. [Name's] motion for a hearing, and denying [Center's] motion to deny a hearing and to disqualify Dr. [Name].]

I. Background [Summarize facts.]

II. Analysis

III. Conclusion

[Signature, Date]

Name

Commissioner of Food and Drugs [or delegate, Title]

[Date]

By Certified Mail [or other documented method of transmission] - **Return Receipt Requested**

[CI Name]
[Address]

[Name of Counsel]
[Address]

[Name of Center's Counsel]
[Address]

Re: In the Matter of [CI's Name]

Commissioner's Decision

Dear Dr. [INVESTIGATOR] [and/or COUNSEL]:

Please see the enclosed Presiding Officer's Report in the above referenced matter, dated [Date], which I am affirming and adopting [in part]. I have found that you [did] [did not] repeatedly or deliberately fail to comply with the requirements of [21 CFR Part ###], or [did] [did not] submit to FDA or the sponsor false information in any required report.

[Additional supporting information, as applicable]

Further, by this letter, I am providing a copy of this Decision to counsel for the Center [Center's name] and to the Division of Dockets Management to be placed on display in the public reading room, and posted on FDA's website.

Sincerely,

[Signature]
[Name]
Commissioner of Food and Drugs [or
delegate]

Enclosure

bcc:

*[To blind copy electronically, send to the relevant party at
firstname.lastname@fda.hhs.gov; for hardcopy distribution at the White Oak
(WO) campus, include the building and room numbers]*

OCC; WO31/WO32

DFOI; HFI-30

OGCP; WO32-5129

ORA, Division of Enforcement (DE), Office of Enforcement and Import Operations (OEIO), Office of Operations (OO); WO32

[Relevant District Office – District Personnel, including the District Director; Director, Investigations Branch; and the District Investigator(s)]

CDER, OSI; WO51

CBER, BIMO Group; HFM-664

CVM, BIMO Group; HFV-234

CDRH, BIMO Group; WO66, BIMO@cdrh.fda.gov

CFSAN, BIMO Group; HFS-205

CFSAN, OCD; HFS-265

[Originating Center – Center files and distribution]

[Notice to Sponsor of Investigator's Disqualification]

[DATE]

[SPONSOR]
[ADDRESS]

Regarding: Disqualification of [INVESTIGATOR]

Dear [SPONSOR]:

The purpose of this correspondence is to inform you that [INVESTIGATOR] is no longer eligible to receive investigational [DRUGS OR DEVICES] and is no longer eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, effective [DATE]. Please see the enclosed [COMMISSIONER'S DECISION, OR OTHER DOCUMENT EVIDENCING DISQUALIFICATION] for the basis for the disqualification of [INVESTIGATOR] under [RELEVANT PROVISION: 21 CFR 312.70(b) OR 21 CFR 511.1(c)(2) OR 21 CFR 812.119(b)]. Each investigational exemption and each approved application submitted under 21 CFR Part [INSERT 314 OR OTHER RELEVANT PROVISIONS IF A DEVICE, OR A NEW ANIMAL DRUG] containing data reported by an investigator who has been determined to be ineligible to receive test articles will be examined to determine whether the investigator has submitted unreliable data that are essential to the continuation of the investigation or essential to the [IF DEVICES, ADD "clearance or"] approval of any marketing application [RELEVANT PROVISION: (21 CFR 312.70(c)) OR (21 CFR 511.1(c)(3)) OR (21 CFR 812.119(c))].

[OPTION 1 – ONGOING STUDIES – INSERT FOLLOWING PARAGRAPH:

If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, the Commissioner will notify you, the sponsor, and you will have an opportunity for a regulatory hearing under 21 CFR part 16 [RELEVANT PROVISION: (21 CFR 312.70(d)) OR (21 CFR 511.1(c)(4)) OR (21 CFR 812.119(d))]. If a danger to the public health exists, however, the Commissioner will terminate the investigational exemption immediately and notify you of the termination. You will then have an opportunity for a regulatory hearing before FDA under Part 16 on the question of whether the investigational exemption should be reinstated [RELEVANT PROVISION: (21 CFR 312.70(d)) OR (21 CFR 511.1(c)(4)) OR (21 CFR 812.119(d))].]

[OPTION 2 – APPROVED PRODUCTS – INSERT FOLLOWING PARAGRAPH:

If the Commissioner determines after the unreliable data submitted by the investigator are eliminated from consideration, that continued [IF DEVICES ADD “clearance or”] marketing approval of the product for which the data were submitted cannot be justified, the Commissioner will proceed to [IF DEVICES ADD “rescind clearance or”] withdraw approval of the product in accordance with the applicable provisions of the Federal Food, Drug, and Cosmetic Act [RELEVANT PROVISION: (21 CFR 312.70(e)) OR (21 CFR 511.1(c)(5)) OR (21 CFR 812.119(e))].]

[NOTE: IF BOTH OPTIONS 1 & 2 APPLY, COMBINE RELEVANT LANGUAGE.]

FDA may contact you in the future to request additional information concerning this matter. If you have questions about this letter, please contact:

[NAME/ADDRESS/TELEPHONE # OF APPROPRIATE REVIEW DIVISION]

Sincerely yours,

[SIGNATURE OF CENTER DIRECTOR OR DELEGEE]

[PRINTED NAME]
[CENTER]

Enclosures:

[ENCLOSE REDACTED COPIES OF RELEVANT DOCUMENTS DESCRIBING THE BASIS FOR DISQUALIFICATION. IF REDACTED DOCUMENTS ARE POSTED, IT MAY BE PREFERABLE TO REFERENCE THE LINK(S) IN THE BODY OF THE LETTER]

Part 16 Regulations

bcc:

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[Originating Center – Center files and distribution]

[Notice to IRB of Investigator's Disqualification]

[DATE]

[CONTACT NAME]

[IRB]

[ADDRESS]

Regarding: Disqualification of [INVESTIGATOR]

Dear [DR./MR./MS. CONTACT NAME]:

The purpose of this correspondence is to inform you that [INVESTIGATOR] is no longer eligible to receive investigational [DRUGS OR DEVICES] and is no longer eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, effective [DATE]. Please see the enclosed [COMMISSIONER'S DECISION, OR OTHER DOCUMENT EVIDENCING DISQUALIFICATION] for the basis for the disqualification of [INVESTIGATOR] under [RELEVANT PROVISION: 21 CFR 312.70(b) OR 21 CFR 812.119(b)].

The [CENTER] of the Food and Drug Administration (FDA) inspected the clinical studies of investigational [DRUGS OR DEVICES] conducted by [INVESTIGATOR] and concluded that [HE/SHE] repeatedly or deliberately failed to comply with applicable requirements for the conduct of clinical trials, and/or repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report. The inspection was part of FDA's Bioresearch Monitoring Program, which is designed to evaluate the conduct of research and to ensure that the rights, safety, and welfare of the human subjects of those studies have been protected.

Your Institutional Review Board (IRB) was identified by [INVESTIGATOR] as having responsibility for the review and approval of [THE or, ONE OR MORE OF THE] clinical [STUDY/STUDIES] conducted by [INVESTIGATOR]. We are notifying you so that your IRB will take appropriate steps to protect the rights, safety, and welfare of any subjects who may be involved in studies conducted by [INVESTIGATOR].

Should you have any questions or concerns regarding this letter, please contact me by letter at the address given below.

Sincerely,

[SIGNATURE]

[NAME, TITLE, OFFICE, CENTER, ADDRESS]

Enclosure: Redacted copy of [COMMISSIONER'S DECISION OR OTHER DOCUMENT EVIDENCING DISQUALIFICATION] issued to [INVESTIGATOR] on [DATE]

bcc:

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[Originating Center – Center files and distribution]