FDA STAFF MANUAL GUIDES, VOLUME IV - AGENCY PROGRAM DIRECTIVES

COMPLIANCE ACTIVITIES

SMG 7711 – DISQUALIFICATION OF A CLINICAL INVESTIGATOR: THE HEARING PROCESS

Effective Date: June 20, 2008

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 entitled to receive investigational new drugs (including biologics), devices, and new animal drugs (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 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.

- The Commissioner has delegated the authority to perform his functions to the officials listed in Staff Manual Guide (SMG) 1410.21. This would include the authority to determine the eligibility of a clinical investigator to receive investigational articles. When the term "Commissioner" is used in this document, the term includes the Commissioner's designee.

- All documents for the Commissioner's review and decision are routed through and by the Office of Executive Secretariat (OES) unless stated otherwise and should have a cover memo 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. Director, Division of Compliance Management and Operations (DCMO), Office of Enforcement (OE), Office of Regulatory Affairs (ORA). The Director, DCMO, 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.

B. 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.[1]

C. Disqualification of a Clinical Investigator. A process through which a decision is made that a clinical investigator is ineligible to receive investigational new drugs (including biologics), devices, or new animal drugs.

D. 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

[1] 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).

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.[2]

E. Motion for Summary Decision. A written brief explaining the issue(s) in the proceeding to the Presiding Officer and requesting a determination. The determination, also known as a Summary Decision, will be incorporated in the Presiding Officer's Report.

F. Presiding Officer. An FDA employee to whom the Commissioner delegates authority to conduct a regulatory hearing,[3] or consistent with 5 CFR 930.209(b) or (c), an administrative law judge to whom such authority is delegated (21 CFR 16.42).

G. Repeated Violation. More than one violation, including the same violation, in one or more studies.[4]

H. 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 request for a Part 16 hearing, the agency observes separation of functions, even though under 21 CFR 16.44(b), 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 the separation of functions has been adopted as a matter of policy.

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

[2] 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)).

[3] See SMG 1410.29, 1.c. (http://www.fda.gov/smg/vol2/1410/1410_29.html) for a list of FDA staff who have been delegated as authorized to serve as presiding officers for Part 16 hearings.

[4] 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 Chaovanee 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).

participating human 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 when FDA has information that one or both of the following conditions exist:
  - The clinical investigator repeatedly or deliberately failed to comply with applicable requirements for conduct of clinical trials, and/or
  - The clinical investigator deliberately or repeatedly submitted false information to FDA or the sponsor 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 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 clinical investigator with a Notice of Opportunity for Hearing (NOOH) under 21 CFR Part 16, Regulatory Hearing before the Food and Drug Administration.

- 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, DCMO, who will send a copy of any response to the Office of the Chief Counsel (OCC), the Director, Good Clinical Practice Program (GCPP), and the Center's BIMO unit. Within ten days of receiving the NOOH, the clinical 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;
- Request additional time to respond to the NOOH; or
- Request a hearing.

1. Fails to respond or declines hearing - If the clinical investigator fails to respond to the NOOH by the deadline stipulated in the NOOH, or declines a hearing and requests that the agency make a determination based on the available information, the Director, DCMO, informs the Center and the Director, GCPP, of the clinical investigator's failure to respond or declination. Within sixty days, and based on the available information, the Center BIMO unit prepares, in consultation with the Center's counsel (i.e., OCC counsel

from that Center's team), a Decision Memorandum and Notice of Disqualification. The Center forwards these documents to the Commissioner for review and decision, with a copy to the Director, GCPP. (See section 5.C.1 of this document.)

2. Requests additional time to respond – If the clinical investigator requests additional time to respond, the Director, DCMO, 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 clinical investigator within five days of receipt of the clinical investigator's request. The Director, DCMO, will send a copy or otherwise notify the Center and the Director, GCPP, of the decision whether to allow additional time to respond to the NOOH.

3. Requests a hearing – 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)). If the clinical investigator requests a hearing:

a. Generally, within one day, the Director, DCMO, forwards a copy of the request to the Center, and the Director, GCPP.

b. Generally, within one day, the Director, GCPP, assigns a Project Manager to the hearing request.

c. Generally, within one day, the Project Manager forwards the hearing request to OCC and requests that OCC designate counsel to work with the Presiding Officer[5] and represent the Commissioner during the hearing process.

d. Within seven days of receipt of the request for a hearing, OCC will provide to the Project Manager the name of the counsel to work with the Presiding Officer (if requested) and represent the Commissioner. In consultation with the Presiding Officer, the Project Manager may identify consultants for use by the Presiding Officer (e.g., a medical officer, scientist to provide scientific/technical advice).

e. Within 60 days of receipt of the request for a hearing, the Center, with the assistance of Center counsel, may evaluate the hearing request to determine whether the clinical 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 Request to Deny the Hearing and to Disqualify, with accompanying memorandum. (See Attachment D.)

[5] The Administrative Law Judge (ALJ) is authorized to act as Presiding Officer by the Commissioner. (21 CFR 16.42(a))

Generally, within one day, the Project Manager will forward the Center's Request to Deny the Hearing and to Disqualify to the Commissioner and Commissioner's counsel.

The Commissioner, with the assistance of counsel will review the Request 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, the Commissioner, with the assistance of counsel, will issue a Commissioner's Decision and a Notice of Disqualification (see Attachments E and A), disqualifying the clinical investigator. The Commissioner's Decision will explain why the hearing was denied. (See section 5.C.2 of this document.) The Commissioner will send the Commissioner's Decision and Notice of Disqualification to the Project Manager. Within seven days of receipt, the Project Manager will forward the Notice of Disqualification and Commissioner's Decision to the clinical investigator and Center.

If the Commissioner determines that the material submitted by the clinical 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 days of receipt, the Project Manager will forward the decision letter to the clinical investigator and Center.

f. If the Center does not file a Request to Deny the Hearing and to Disqualify, the clinical investigator's request for hearing is deemed granted.

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 his 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 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 conference[6] 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 request for hearing is granted, the Center and/or the clinical investigator may submit Motions for Summary Decision within the timeframe specified at the telephone conference, generally within ninety days.[7] 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 counsel to review, and revise, if necessary. Center 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 Motion for Summary Decision to the Presiding Officer, Project Manager, and Center's counsel.

2. Review of Motion(s) for Summary Decision -Within ninety days of receipt, the Presiding Officer, with the assistance of counsel (if requested), will review the Motion(s) for Summary Decision and any other matters officially noticed[8], and issue a Summary Decision[9] (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

[6] The process described in section 6.A.3.e of this document should be completed before the Project Manager arranges the telephone conference.

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

[8] 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.

[9] The Summary Decision will be incorporated in a Presiding Officer's Report.

explains whether the evidence presented shows that the clinical investigator has repeatedly or deliberately violated the regulations or deliberately or repeatedly submitted false information to FDA or the sponsor in any required report.

a. If the Presiding Officer agrees with the Center that there is no genuine and substantial issue of fact to be decided at a hearing regarding whether the clinical investigator has repeatedly or deliberately violated the regulations or deliberately or repeatedly submitted false information to FDA or the sponsor in any required report, the Presiding Officer issues a Summary Decision[9] granting the Center's Motion in whole or in part, and recommending that the clinical investigator be disqualified. A hearing will not be scheduled.

b. If the Presiding Officer determines that the materials submitted by the clinical investigator do raise an issue of fact as to whether the clinical investigator violated the regulations and/or submitted false information in any required report to the sponsor or FDA, the Presiding Officer issues a Summary Decision,[9] denying the Center's Motion. A hearing will be scheduled.

c. If the Presiding Officer determines that the materials submitted by the clinical investigator and Center do not raise any issue of fact as to the clinical 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 clinical investigator not be disqualified. (See Attachment B.)

The Project Manager, within seven days, forwards the Presiding Officer's Report to the Commissioner (or delegate). The Commissioner, on his own initiative or at the request of either party,[10] may review the Presiding Officer's Report and all related materials (21 CFR 16.26(c)). Within ninety days of receipt of the Presiding Officer's Report, the Commissioner will issue a decision on whether to disqualify the clinical investigator. (See section 6.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 ten days of the Presiding Officer issuing the letter, the Project Manager, with the Presiding Officer, notifies the Center, the clinical investigator, and their respective attorneys to arrange a date (preferably within thirty 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

[10] The Center can request that the Commissioner review the decision and all related materials (21 CFR 16.26(c)).

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 ninety 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 that 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. 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 (see Attachment E) regarding the eligibility of the clinical investigator to receive investigational articles (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 D) and issue a decision within ninety days. The Commissioner may accept, in whole or in part, the findings of the Center regarding the violations alleged to be committed by the clinical investigator. If the Commissioner adopts the Center's recommendation for disqualification of the clinical investigator, the Commissioner will sign the Decision Memorandum and the Notice

of Disqualification (see Attachment C) prepared by the Center (see section 5.A.1.) and forward them 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;[11] and

(3) Provides a copy of the Notice of Disqualification to the Center and Center's counsel.

Within seven days of the confirmed delivery,[11] the Center issues letters to the sponsor(s) and Institutional Review Board(s) (IRB(s)) of any investigation(s) in which the clinical investigator has been named as a participant.[12, 13] The letters should explain that the clinical investigator is disqualified and may attach a copy of the Notice of Disqualification. The letter should ask the sponsor(s) to examine all investigational[14] and marketing[15] 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 fourteen days of confirmed delivery,[11] 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, DCMO, so that the investigator's name can be included in the list of disqualified clinical investigators on FDA's website [http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm].

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[11] 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.

[12] FDA Information Disclosure Manual, Section IV, Sharing Non-Public Information With Sponsors And Institutional Review Boards.

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

[14] Investigational New Drug Application, Investigational Device Exemption, and Notice of Claimed Investigational Exemption for a New Animal Drug.

[15] 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.

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 clinical investigator.[16] Within seven days, the Project Manager will send the letter to the clinical investigator by certified mail (return receipt) or other documented method of transmission. A copy of the letter (and memo, if any) is sent to the Center.

Within fourteen 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 website, as appropriate. [http://www.fda.gov/foi/clinicaldis/default.htm.]

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

If the Commissioner grants the Center's Request to Deny the Hearing and to Disqualify (see section 5.A.3.e.), the Commissioner, with the assistance of counsel, will issue a Notice of Denial of Hearing and Disqualification (see Attachment A) 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;[11] and

(3) Provides a copy of the Notice of Denial of Hearing and Disqualification to the Center and Center's counsel.

Within seven days of the confirmed delivery,[11] the Center issues letters to the sponsor(s) and Institutional Review Board(s) (IRB(s)) of any investigation(s) in which the clinical investigator has been named as a participant.[17, 18] The letters should explain that the clinical investigator is disqualified and may attach a copy of the Notice of Denial of Hearing and Disqualification. The letter should ask the sponsor(s) to examine all investigational[19] and marketing[20] applications containing

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

[17] FDA Information Disclosure Manual, Section IV, Sharing Non-Public Information With Sponsors And Institutional Review Boards.

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

[19] Investigational New Drug Application, Investigational Device Exemption, and Notice of Claimed Investigational Exemption for a New Animal Drug.

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 fourteen days of confirmed delivery, 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 website, as appropriate [http://www.fda.gov/foi/clinicaldis/default.htm]; and

(3) Forward information about the clinical investigator's disqualification to the Director, DCMO, so that the investigator's name can be included in the list of disqualified clinical investigators on FDA's website [http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm].

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 his own initiative (21 CFR 16.26(c)). The Presiding Officer's Summary Decision is forwarded to the Commissioner, who will issue, within ninety days, a written Commissioner's Decision[21] (see Attachment F) either disqualifying the clinical investigator from being eligible to receive investigational articles, or determining that the clinical investigator did not repeatedly or deliberately fail to comply with the regulations or deliberately or repeatedly submit false information to FDA or to the sponsor 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 clinical investigator should be disqualified, that is, he/she has repeatedly or deliberately failed to comply with the requirements in the regulations, or has deliberately or repeatedly submitted false information to FDA or the sponsor in any required report, within the above ninety days, the Commissioner, with the assistance of counsel, will issue a Commissioner's Decision. The Commissioner, with the assistance of counsel, will also prepare a Notice of Disqualification (see Attachment C) to inform the clinical investigator that he/she has

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[20] 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.

[21] 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.

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 clinical investigator did not violate all the regulations cited by the Center in the NOOH, the clinical investigator may still be disqualified if he/she repeatedly or deliberately violated any regulations cited, or deliberately or repeatedly submitted false information to FDA or the sponsor in a 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 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; and
(3) Provides a copy of the Notice of Disqualification and Commissioner's Decision to the Center and Center's counsel.

Within seven days of the confirmed delivery,[11] the Center issues letters to the sponsor(s) and IRB(s) of any investigation(s) in which the clinical investigator has been named as a participant.[12, 13] The letters should explain that the clinical investigator is disqualified and may attach a copy of the Notice of Disqualification. The letter should ask the sponsors to examine all investigational[14] and marketing[15] 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 fourteen 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 website, as appropriate [http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm]; and
(3) Forward information about the clinical investigator's disqualification to the Director, DCMO, so that the investigator's name can be included in the list of disqualified clinical investigators on FDA's website [http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm].

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.[22] (See Attachment B.) Within seven days of receipt of the Commissioner's Decision, the Project Manager will send a copy of the Commissioner's Decision to the clinical investigator by certified mail (return receipt) or other documented method of transmission. A copy of the Commissioner's Decision is sent to the Center.

Within fourteen days of confirmed delivery,[11] 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 website [http://www.fda.gov/foi/clinicaldis/default.htm].

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 ninety days of receipt.[23] (See Attachment F.) 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 or letter.

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 clinical investigator repeatedly or deliberately failed to comply with the requirements in the regulations, or has deliberately or repeatedly submitted false information to FDA or the sponsor in a required report, the Commissioner with the assistance of counsel will prepare a Commissioner's Decision and a Notice of Disqualification (see Attachment A) and send it to the Project Manager.

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 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;[11] and

(3) Provides a copy of the Notice of Disqualification and Commissioner's Decision to the Center.

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[22] 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.

[23] 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.

Within seven days of the confirmed delivery,[11] the Center issues letters to the sponsor(s) and IRB(s) of any investigation in which the clinical investigator has been named as a participant.[12, 13] The letters should explain that the clinical investigator is disqualified and may attach a copy of the Notice of Disqualification. The letter should ask the sponsor(s) to examine all investigational[14] and marketing[15] 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 fourteen days of confirmed delivery,[11] 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 website [http://www.fda.gov/foi/clinicaldis/default.htm]; and

(3) Forward information about the clinical investigator's disqualification to the Director, DCMO, so that the investigator's name can be included in the list of disqualified clinical investigators on FDA's website [http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm].

b. Commissioner Determines the Clinical Investigator Should Not Be Disqualified

If after reviewing the administrative record, including the Presiding Officer's Report, the Commissioner determines not to disqualify, within ninety days, the Commissioner with the assistance of counsel will prepare a Commissioner's Decision and/or letter. (See Attachments E and F.) 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 his/her counsel by certified mail (return receipt) or other documented method of transmission. A copy of the letter is sent to the Center.

Within fourteen days of confirmed delivery,[11] 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 website. [http://www.fda.gov/foi/clinicaldis/default.htm].

D. Administrative Record and Posting of Documents

Copies of all documents are sent to the Project Manager for purposes of recordkeeping (administrative record). The Center is responsible for forwarding the documents to the Center's FOI contact and DCMO, so that as appropriate, all applicable documents may be

posted on the agency website (after redaction), e.g., Notice of Disqualification, Notice of Denial and Disqualification, the Presiding Officer's Report, Commissioner's Decision.

6. EFFECTIVE DATE

This FDA Staff Manual Guide is effective as of June 20, 2008.

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 Swisher Pfaender Senior Health Policy Analy Good Clinical Practice Pro (GCPP), Office of the Commissioner (OC)	Joanne R. Less, Ph.D., Director, Good Clinic Practice Program (HFD-34)

Attachment A

[Date]

By Certified Mail - Return Receipt Requested

[CI Name]
[Address]

[Name of Counsel]
[Address]

Notice of Denial of Hearing and Disqualification of Eligibility to Receive Investigational [Product]

Dear Dr. [CI Surname] [and Counsel]:

I have reviewed the record of the regulatory proceeding involving Dr. [CI Name], including [list appropriate records, e.g., Request for Hearing Denial, [Center's] Motion for Summary Decision, Dr. [Name]'s Memorandum in Opposition, etc.]. Based upon my review, I have concluded that there is no genuine and substantial issue of fact with regard to whether Dr. [Name] repeatedly and deliberately violated 21 CFR [312.70, 511, 812] in connection with [an investigational new drug study] [investigational new animal drug study][an investigational device study] of [name of product]. I am therefore granting [Center's] Request for Hearing Denial and, consistent with 21 CFR [312.70(b) or 511.1(c) or 812.119], I have determined that Dr. [Name] is no longer eligible to receive investigational [product(s)]. Under authority delegated to me by the Commissioner of Food and Drugs, I am issuing this Commissioner's Decision disqualifying Dr. [Name] from eligibility to receive investigational [product]. The reasons for this determination are set forth in the enclosed decision.

Dr. [Name] may seek to have his eligibility to receive investigational [product(s)] reinstated, pursuant to 21 CFR [312.70(f), 511.1(c)(6), 812.119(f)] upon presentation of adequate assurances that the investigator will employ investigational [product] solely in compliance with the provisions of [applicable regulations, i.e., 21 CFR Parts 50, 54, 56, 312, 511, 812].

Sincerely,

Commissioner of Food and Drugs [or designee]

[Enclosure]

Attachment B

[Date]

By Certified Mail - Return Receipt Requested

[CI Name]
[Address]

[Name of Counsel]
[Address]

Notice of Continuation of Eligibility to Receive Investigational [Product]

Dear Dr. [CI Surname] [and Counsel]:

I have reviewed the record of the regulatory proceeding involving Dr. [CI Name], including [list appropriate records, e.g., Request for Hearing Denial, [Center's] Motion for Summary Decision, Dr. [Name]'s Memorandum in Opposition, etc.]. Based upon my review, I have concluded that Dr. [Name] did not repeatedly or deliberately violate 21 CFR Part [312, 511, 812] in connection with [an investigational new drug study] [an investigational new animal drug study] [an investigational device study] of [name of product]. I am therefore granting Dr. [Name]'s Motion and, consistent with 21 CFR [312.70(b) or 511.1(c) or 812.119]. Under 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. [Name] continues to be eligible to receive investigational [product(s)]. The reasons for this determination are set forth in the enclosed decision.

Sincerely,

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

[Enclosure]

Attachment C

[Date]

By Certified Mail - Return Receipt Requested

[CI Name]
[Address]

[Name of Counsel]
[Address]

Notice of Disqualification of Eligibility to Receive Investigational [Product]

Dear Dr. [CI Surname] [and Counsel]:

I have reviewed the record of the regulatory proceeding involving Dr. [CI Name], including [list appropriate records, e.g., [Center's] Motion for Summary Decision, Dr. [Name]'s Motion in Opposition, Presiding Officer's Report, etc.]. Based upon my review, I have concluded that there is no genuine and substantial issue of fact with regard to whether Dr. [Name] repeatedly or deliberately violated 21 CFR Part [312, 511, 812] in connection with [an investigational new drug study] [an investigational new animal drug study][an investigational device study] of [name of product]. I am therefore granting [Center's] Motion for Summary Decision and consistent with 21 CFR [312.70(b) or 511.1(c) or 812.119], I have determined that Dr. [Name] is no longer eligible to receive investigational [product(s)]. Under authority delegated to me by the Commissioner of Food and Drugs, I am issuing this Commissioner's Decision disqualifying Dr. [Name] from eligibility to receive investigational [product]. The reasons for this determination are set forth in the enclosed decision.

Dr. [Name] may seek to have his eligibility to receive investigational [product(s)] reinstated, pursuant to [312.70(f), 511.1(c)(6), 812.119(f)] upon presentation of adequate assurances that the investigator will employ investigational [product] solely in compliance with the provisions of [applicable regulations, i.e., 21 CFR Parts 50, 54, 56, 312, 511, 812].

Sincerely,

[Signature]
Name
Commissioner of Food and Drugs (or designee)

[Enclosure]

Attachment D

Routing/Clearance, Center Decision Memorandum

Date:

To: Commissioner of Food and Drugs

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 Disqualification of [Name], MD, City, State – ACTION

ACTION REQUESTED

I request your decision, under 21 CFR Parts 16 and [312, 511, 812], regarding our recommendation (below) to disqualify [Name], from being eligible to receive investigational [new drugs, new animal drugs, devices]. If you agree with the recommendation, I request your signature on the last page of this recommendation, and on the attached "Notice of Disqualification of Eligibility to Receive Investigational [Product: New Drugs, , New Animal Drugs, Devices]" (Attachment 1), to be issued to Dr. [Name].

BACKGROUND

[Provide summary of case.]

CONCLUSION

DECISION

Pursuant to 21 CFR Parts 16 and [312, 511, 812], the Food and Drug Administration hereby disqualifies [Name, Title] from receiving investigational [products].

Approved _____ Disapproved _____

_____ _____

Signature Date
Name
Title

ATTACHMENTS

Notice of Disqualification of Eligibility to Receive Investigational [Product: New Drugs, Biologics, Devices, New Animal Drugs]; [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)]

Attachment E

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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

Dr. [NAME]

FROM RECEIVING INVESTIGATIONAL NEW [PRODUCTS]

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, 812], Dr. [Name] be disqualified from receiving investigational [products]. [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), 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 [##]. I am therefore granting [Center's] request to deny Dr. [Name's] request for a hearing and to disqualify Dr. [Name] from receiving investigational [products].] [Under authority delegated to me by the Commissioner of Food and Drugs, I am issuing this Commissioner's Decision disqualifying Dr. [Name] from eligibility to receive investigational drugs.]

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 [##]. I am therefore granting Dr. [Name's] request for a hearing, and denying [Center's] request to deny a hearing and to disqualify Dr. [Name] from receiving investigational [products].]

I. Background [Summarize facts.]

II. Analysis

III. Conclusion

[Signature, Date]
Name
Commissioner of Food and Drugs [or designee, Title]

Attachment F

[Date]

By Certified Mail - 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. [CI Surname] [and 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 ###].

[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 designee]

[Enclosure]