U.S. FOOD & DRUG ADMINISTRATION

NOTICE OF OPPORTUNITY FOR HEARING (NOOH)

VIA UNITED PARCEL SERVICE

February 25, 2021

Naveed Razzaque, M.D.
3165 McKelvey Road, Suite 102
Bridgeton, Missouri 63044

Dear Dr. Razzaque:

The Center for Drug Evaluation and Research (the Center) of the U.S. Food and Drug Administration (FDA) has information indicating that you repeatedly or deliberately submitted false information to FDA or to the sponsor in required reports. These violations provide the basis for withdrawal of your eligibility as a clinical investigator to receive investigational new drugs and to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

Pursuant to section 312.70(a) of Title 21 of the Code of Federal Regulations (21 CFR 312.70(a)), the Center informed you by letter titled "Notice of Initiation of Disqualification Proceedings and Opportunity to Explain" (NIDPOE) dated June 4, 2020, of the specific matters complained of, and offered you an opportunity to respond in writing or at an informal conference. The NIDPOE Letter also offered you the option of entering into a consent agreement with FDA, thereby terminating any administrative proceeding against you. In response to the NIDPOE Letter, you submitted documentation dated July 7, 2020, and requested an informal conference with FDA, which took place on September 21, 2020. Following the conference, you submitted additional documentation dated October 14 (October 14 response) and October 15, 2020.

After a review of all available information, the Center has concluded that your written explanations are unacceptable because they fail to adequately address the violations set forth below.

Accordingly, you are being offered an opportunity for a regulatory hearing pursuant to 21 CFR parts 16 and 312, to determine whether you are entitled to receive investigational new drugs and to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA. You have the right to be advised and

represented by counsel at all times. Any regulatory hearing on this matter will be governed by the regulations in 21 CFR part 16 and by FDA's guidelines on electronic media coverage of administrative proceedings, 21 CFR part 10, subpart C. Enclosed you will find copies of these regulations. A listing of the specific violations follows. These are matters that would be considered at the regulatory hearing, if granted. The applicable provision of the CFR is cited below.

You repeatedly or deliberately submitted false information to the sponsor [21 CFR 312.70(a)].

As a clinical investigator for Protocol [redacted (b) (4)], you were required to perform on-site protocol-required procedures and telephone-call assessments at certain timepoints.

FDA has concluded that you repeatedly or deliberately submitted false information to the sponsor in the form of falsified study records. Specifically:

1. Protocol [redacted (b) (4)] required that a total of 14 scheduled on-site study visits be conducted for each subject. Specifically, during scheduled on-site study visits, you were required to conduct the following medical procedures:

    a. Primary efficacy endpoint assessments: time to first occurrence of any component of the composite of major adverse cardiovascular events (MACE), including cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, emergent/elective coronary revascularization, or hospitalization for unstable angina

    b. Physical exam and clinical assessments (blood pressure, heart rate, height, and weight)

    c. Laboratory assessments: serum chemistry, fasting lipid panel, and hemoglobin A1c

    d. Adverse event (AE) assessments

    e. Concomitant medication review

    Subject [redacted (b) (6)] (also referred to as Subject [redacted (b) (6)]) passed away on [redacted (b) (6)]. You signed and dated study records falsely indicating that required study procedures, such as primary MACE efficacy endpoint assessments, physical exams, AE assessments, and concomitant medication assessments, were completed for two protocol-required study visits occurring after this date.

You also submitted falsified records for several more study visits between November 22, 2016, and September 28, 2018.

These falsified records were submitted to the sponsor to support data (including primary efficacy data) collected at your site during the conduct of the study.

In your written responses, including your response to the NIDPOE letter and your October 14 response, you reiterated that falsified records were attributable to the misconduct of a site manager that you had little control over, and that telephone assessments were delegated to this site manager. In addition, you indicated that FDA misrepresented Subject (b) (6)'s clinical status when the falsification occurred, because the subject had stopped investigational product at that time and had agreed that the "site would continue to monitor Subject (b) (6) via telephone calls, and that no further in-office visits or tests would be performed." You also stated that "only some of these falsified records were presented to the study investigators" and that you and other investigators initially reviewed telephone contact records for significant issues and contacted the subject directly only if the initial contact record suggested there was a possible issue. You stated that because falsified records presented to you and other investigators noted an asymptomatic patient, and because these records revealed no suspected adverse events requiring follow-up, the study investigators had no reason to contact Subject (b) (6) directly.

2. Protocol (b) (4) required a total of nine telephone-call assessments (in addition to on-site study visits) scheduled every six months starting after Visit 4, to question subjects about MACE efficacy endpoint assessment, AEs, changes in concomitant medication, and major issues with the investigational product (losses or noncompliance).

   As noted above, Subject (b) (6) passed away on (b) (6). Study records falsely documented that study staff personnel spoke directly with Subject (b) (6) and completed three protocol-required telephone-call assessments, including primary MACE efficacy endpoints, AEs, concomitant medications, and investigational product assessments, after this date (between January 6, 2017, and December 27, 2017).

   These falsified records were submitted to the sponsor to support data (including primary efficacy data) collected at your site during the conduct of the study.

   In your October 14 response, you stated that (1) falsified telephone call records were limited to AE assessments, and (2) Subject (b) (6) was being monitored only minimally by the site since the subject stopped investigational product.

Your responses to both points are unacceptable because they fail to adequately address the violations set forth above. You reiterated that (1) data falsification was perpetrated by the site manager to whom certain trial activities were "delegated," and (2) you reviewed falsified records only from a medical standpoint. However, as stated previously, as a clinical investigator, it is your responsibility to ensure that the data collected from study subjects are accurate and can be relied upon in any analyses of the study endpoints. We would like to reiterate that when you signed the Statement of the Investigator, Form FDA 1572, you agreed to provide accurate information to the sponsor and to ensure that you would comply with FDA regulations related to the conduct of the clinical investigations of the investigational drugs; and you agreed to ensure that all associates, colleagues, and employees assisting in the conduct of the study or studies were informed about their obligations in meeting their commitments.

In addition, your response is unacceptable because you indicate that the Subject [redacted] (b) (6) was asymptomatic and records show no suspected adverse events that required follow-up; therefore, there was no reason to contact the subject. However, study records indicate that Subject [redacted] (b) (6) had ongoing unresolved AEs, some of which were considered serious. One example is the subject's in-patient hospitalization from [redacted] (b) (6) to [redacted] (b) (6) (before the subject's death in [redacted] (b) (6)), which required follow-up based on the investigational plan you agreed to follow when you signed Form 1572. Protocol [redacted] (b) (4) indicates that serious adverse events will be observed and monitored carefully until the event resolves, stabilizes, or returns to baseline. There were multiple documented serious adverse events, including two records of in-patient hospitalization, with no clear indication that these events were resolved or that you followed up with the subject to determine resolution of the issues noted.

Your response is also inadequate when you state that you believed Subject [redacted] (b) (6) was "lost to follow-up," and indicate that falsified telephone records submitted to the sponsor were limited to AE assessments and did not include primary efficacy data. According to study records, the sponsor instructed you to continue following the subject via telephone call visits, which still included collection of study data such as AEs, MACE efficacy assessments, and concomitant medications. As we mentioned previously in the NIDPOE Letter issued on June 4, 2020, falsified telephone call records included primary MACE efficacy endpoint assessment data and AE assessment data.

Your request for a hearing should be made in writing within ten (10) business days after your receipt of this letter, and should be directed to Armando Zamora, Acting Director, Division of Enforcement, Office of Strategic Planning and Operational Policy, ORA, FDA, 12420 Parklawn Drive, ELEM-4038, Rockville, MD 20857, telephone (301) 796-5723, email: Armando.Zamora@fda.hhs.gov. If no response to this letter has been received by that

time, you will be deemed to have waived any right to a regulatory hearing, and a decision in this matter will be made based on the facts available to FDA. No hearing will be held.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that warrants a hearing. Pursuant to 21 CFR 16.26, a request for a hearing may be denied, in whole or in part, if the Commissioner or his delegate determines that no genuine and substantial issue of fact has been raised by the material submitted. A hearing will not be granted on issues of policy or law. Written notice of a determination of summary judgment will be provided, explaining the reasons for denial of the hearing.

If you wish to respond but do not desire a hearing, you should contact Armando Zamora within the specified time period and send a written reply containing your response. The letter should state that you waive your right to a hearing, and that you want a decision on the matter to be based on your written response and other information available to FDA.

FDA's offer to enter into a consent agreement, attached to the NIDPOE letter dated June 4, 2020, remains available. Entering into a consent agreement would terminate the administrative procedures but would not preclude the possibility of a corollary judicial proceeding.

No final decision by FDA has been made at this time on your eligibility to continue to receive test articles. Moreover, there will be no prejudgment of this matter if you decline to enter into a consent agreement and decide instead either to request a regulatory hearing or to request that the decision be based on information currently available to FDA.

Please inform Armando Zamora within ten (10) business days whether you wish to request a hearing or have this matter resolved by consent agreement or information available to FDA.

Sincerely,

/Judith McMeekin/
Judith McMeekin, Pharm. D.
Associate Commissioner for Regulatory Affairs

Enclosures:
21 CFR part 10, subpart C
21 CFR part 16
21 CFR 312.70

Cc: Seth A. Mailhot, J.D.
HUSCH BLACKWELL LLP
750 17th Street, NW, Suite 900
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not apply paragraphs (i)(1) and (i)(2) of this section. However, any final guidance document issued according to this provision must contain the elements in paragraphs (i)(1) and (i)(2) of this section.

(j) *Who, within FDA, can approve issuance of guidance documents?* Each center and office must have written procedures for the approval of guidance documents. Those procedures must ensure that issuance of all documents is approved by appropriate senior FDA officials.

(k) *How will FDA review and revise existing guidance documents?* (1) The agency will periodically review existing guidance documents to determine whether they need to be changed or withdrawn.

(2) When significant changes are made to the statute or regulations, the agency will review and, if appropriate, revise guidance documents relating to that changed statute or regulation.

(3) As discussed in paragraph (f)(3) of this section, you may at any time suggest that FDA revise a guidance document.

(l) *How will FDA ensure that FDA staff are following GGP's?* (1) All current and new FDA employees involved in the development, issuance, or application of guidance documents will be trained regarding the agency's GGP's.

(2) FDA centers and offices will monitor the development and issuance of guidance documents to ensure that GGP's are being followed.

(m) *How can you get copies of FDA's guidance documents?* FDA will make copies available in hard copy and, as feasible, through the Internet.

(n) *How will FDA keep you informed of the guidance documents that are available?* (1) FDA will maintain on the Internet a current list of all guidance documents. New documents will be added to this list within 30 days of issuance.

(2) Once a year, FDA will publish in the FEDERAL REGISTER its comprehensive list of guidance documents. The comprehensive list will identify documents that have been added to the list or withdrawn from the list since the previous comprehensive list.

(3) FDA's guidance document lists will include the name of the guidance document, issuance and revision dates, and information on how to obtain copies of the document.

(o) *What can you do if you believe that someone at FDA is not following these GGP's?* If you believe that someone at FDA did not follow the procedures in this section or that someone at FDA treated a guidance document as a binding requirement, you should contact that person's supervisor in the center or office that issued the guidance document. If the issue cannot be resolved, you should contact the next highest supervisor. You can also contact the center or office ombudsman for assistance in resolving the issue. If you are unable to resolve the issue at the center or office level or if you feel that you are not making progress by going through the chain of command, you may ask the Office of the Chief Mediator and Ombudsman to become involved.

[65 FR 56477, Sept. 19, 2000]

Subpart C—Electronic Media Coverage of Public Administrative Proceedings; Guideline on Policy and Procedures

SOURCE 49 FR 14726, Apr. 13, 1984, unless otherwise noted.

§ 10.200 Scope.

This guideline describes FDA's policy and procedures applicable to electronic media coverage of agency public administrative proceedings. It is a guideline intended to clarify and explain FDA's policy on the presence and operation of electronic recording equipment at such proceedings and to assure uniform and consistent application of practices and procedures throughout the agency.

§ 10.203 Definitions.

(a) *Public administrative proceeding* as used in this guideline means any FDA proceeding which the public has a right to attend. This includes a formal evidentiary public hearing as set forth in part 12, a public hearing before a Public Board of Inquiry as set forth in part 13, a public hearing before a Public Advisory Committee as set forth in part

14, a public hearing before the Commissioner as set forth in part 15, a regulatory hearing before FDA as set forth in part 16, consumer exchange meetings, and Commissioner's public meetings with health professionals.

(b) *Advance notice* as used in this guideline means written or telephone notification to FDA's Office of Public Affairs (Press Relations Staff) of intent to electronically record an agency public administrative proceeding.

(c) *Electronic recording* as used in this guideline means any visual or audio recording made by videotape recording equipment or moving film camera, and/or other electronic recording equipment.

[49 FR 14726, Apr. 13, 1984, as amended at 54 FR 9035, Mar. 3, 1989]

§ 10.204 General.

(a) FDA has for many years willingly committed itself to a policy of openness. In many instances FDA has sought to make the open portions of agency public administrative proceedings more accessible to public participation. Similarly, FDA has sought, wherever possible, to allow full written media access to its proceedings, so that members of the press would have the opportunity to provide first-hand reports. However, because electronic media coverage presents certain difficulties that are easier to resolve with advance notice to the agency and all participants, FDA believes that codification of its policy will facilitate and further increase media access to its public administrative proceedings. The agency intends to refer to this guideline when notices of hearing, or individual advisory committee meetings, are published in the FEDERAL REGISTER. Thus, all parties to a proceeding will be on notice that the proceeding may be recorded electronically and any person interested in videotaping or otherwise recording the proceeding will be notified that there are established procedures to be followed.

(b) The designated presiding officer of a public administrative proceeding retains the existing discretionary authority set forth in specific regulations pertaining to each type of administrative proceeding to regulate the conduct of the proceeding over which he or she presides. The responsibilities of the presiding officer, established elsewhere in parts 10 through 16, include an obligation to be concerned with the timely conduct of a hearing, the limited availability of certain witnesses, and reducing disruptions to the proceeding which may occur. Each proceeding varies, and the presiding officer cannot anticipate all that might occur. Discretionary authority to regulate conduct at a proceeding has traditionally been granted to presiding officers to enable them to fulfill their responsibility to maintain a fair and orderly hearing conducted in an expeditious manner.

(c) This guideline provides the presiding officer with a degree of flexibility in that it sets forth the agency's policy as well as the procedures that presiding officers should ordinarily follow, but from which they may depart in particular situations if necessary, subject to the presumption of openness of public proceedings to electronic media coverage. The presiding officer's discretion to establish additional procedures or to limit electronic coverage is to be exercised only in the unusual circumstances defined in this guideline. Even though a presiding officer may establish additional procedures or limits as may be required in a particular situation, he or she will be guided by the policy expressed in this guideline in establishing these conditions. The presiding officer may also be less restrictive, taking into account such factors as the duration of a hearing and the design of the room.

(d) If a portion or all of a proceeding is closed to the public because material is to be discussed that is not disclosable to the public under applicable laws, the proceeding also will be closed to electronic media coverage.

(e) The agency requests advance notice of intent to record a proceeding electronically to facilitate the orderly conduct of the proceeding. Knowledge of anticipated media coverage will allow the presiding officer to make any special arrangements required by the circumstances of the proceeding. The agency believes that this guideline establishes sufficiently specific criteria to promote uniformity.

(f) The agency would like to allow all interested media representatives to

videotape a proceeding in which they have an interest. However, should space limitations preclude a multitude of cameras, the presiding officer may require pool sharing. In such a case, pool sharing arrangements of the resulting videotape should be made between those allowed to film and those who were excluded. Arrangements for who is designated to present the pool and a method of distributing the resulting film or tape may be determined by the established networks' pooling system. However, the agency has a strong commitment to ensuring that media representatives other than the major networks also be able to obtain a copy of the tape at cost. FDA is concerned that if the network pool representative wishes to record only a short portion of a proceeding, but an excluded party wishes to record the entire proceeding, confusion will result. The agency expects the interested media representatives to negotiate a suitable agreement among themselves before commencement of the proceeding. For example, the network pool representatives might agree to record a portion of the proceeding up to a break in the proceeding, at which time, while the network representative is disassembling equipment, another media representative might set up to continue recording. If an agreement cannot be reached before the proceeding, the agency will use the time of receipt of any advance notice to determine the representation for each category of media, e.g., one network reporter, one independent reporter. The agency recommends that parties intending to videotape provide as much advance notice as possible, so that the agency may best respond to the needs of the electronic media.

(g) To ensure the timely conduct of agency hearings and to prevent disruptions, equipment is to be stationary during a proceeding and should be set up and taken down when the proceeding is not in progress. As noted previously, the presiding officer may, at his or her discretion, be less restrictive if appropriate.

(h) The agency recognizes that electronic media representatives may desire only short footage of a proceeding, a facsimile of the proceeding, and/or interview opportunities and may be unnecessarily restricted by requirements for setting up before a proceeding and then waiting until a break in the proceeding before being permitted to take down their equipment. To accommodate this possibility, FDA's Press Relations Staff will attempt to make arrangements to respond to such needs by, for example, requesting that the presiding officer provide a break shortly after commencement of the proceeding to permit take down of equipment.

(i) The agency is making a full commitment to allowing, whenever possible, electronic coverage of its public administrative proceedings subject to the limited restrictions established in this guideline.

§ 10.205 Electronic media coverage of public administrative proceedings.

(a) A person may record electronically any open public administrative proceeding, subject to the procedures specified in this guideline. The procedures include a presumption that agency public proceedings are open to the electronic media. Whenever possible, FDA will permit all interested persons access to record agency public administrative proceedings. Restrictions other than those listed in § 10.206 will be imposed only under exceptional circumstances.

(b) A videotape recording of an FDA public administrative proceeding is not an official record of the proceeding. The only official record is the written transcript of the proceeding, which is taken by the official reporter.

§ 10.206 Procedures for electronic media coverage of agency public administrative proceedings.

(a) To facilitate the agency's response to media needs, a person intending to videotape an FDA public administrative proceeding should, whenever possible, provide advance notice to the Press Relations Staff (HFI–20), Office of Public Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, in writing or by telephone (telephone 301–443–4177), at least 48 hours in advance of the proceeding. The Press Relations Staff will inform

the presiding officer that the proceeding will be attended by representatives of the electronic media, and ascertain whether any special provisions in addition to those set forth in this subpart are required by the presiding officer. If so, the Press Relations Staff will function as a liaison between the presiding officer and the person intending to record the proceeding in facilitating any procedures in addition to those outlined in this subpart. The presiding officer will not deny access for failure to provide a 48-hour advance notice. Any advance notice may describe the intended length of recording if known, the amount and type of equipment to be used, and any special needs such as interviews.

(b) Cameras should be completely set up before a proceeding is scheduled to begin or during a break in the proceeding and should remain standing in the area designated for electronic media equipment. Cameras may be taken down only during breaks or after the hearing is over. Roving cameras will not be permitted during the proceeding. Any artificial lighting should be unobtrusive. Microphones, like cameras, should be in place before the start of a proceeding and may be taken down as indicated in this paragraph.

(c) When space in the hearing room is limited, the presiding officer may restrict the number of cameras or the equipment present. Should such a restriction become necessary, the pool arrangements are the responsibility of the participating media. The agency encourages the network pool to make copies of the tape, film, or other product available at cost to nonpool participants. However, if this is not possible, the agency may need to use the time of receipt of any advance notice to determine the representation for each category, e.g., one network reporter, one independent reporter, etc.

(d) *Off the record* portions of a proceeding may not be videotaped.

(e) Before or during the proceeding, the presiding officer may establish other conditions specific to the proceeding for which the request is being made. These conditions may be more or less restrictive than those stated in this guideline, except that the presiding officer shall observe the agency's presumption of openness of its public proceedings to the electronic media. Only a substantial and clear threat to the agency's interests in order, fairness, and timeliness authorizes the presiding officer to impose additional restrictions. This threat must outweigh the public interest in electronic media coverage of agency proceedings. Additional restrictions shall be narrowly drawn to the particular circumstances. The following factors are listed to assist presiding officers in determining whether the agency's interest is sufficiently compelling to call for the unusual step of imposing additional restrictions. Generally this step is justified when one of the following factors is met:

(1) Electronic recording would result in a substantial likelihood of disruption that clearly cannot be contained by the procedures established in paragraphs (a) through (d) of this section.

(2) Electronic recording would result in a substantial likelihood of prejudicial impact on the fairness of the proceeding or the substantive discussion in a proceeding.

(3) There is a substantial likelihood that a witness' ability to testify may be impaired due to unique personal circumstances such as the age or psychological state of the witness or the particularly personal or private nature of the witness' testimony, if the witness' testimony were electronically recorded.

(f) Before the proceeding, the Press Relations Staff will, upon request, provide written copies of any additional conditions imposed by the presiding officer (as described in paragraph (e) of this section) to requesting members of the media. Any appeals should be made in accordance with paragraph (h) of this section.

(g) The presiding officer retains authority to restrict or discontinue videotaping or other recording of a proceeding, or parts of a proceeding, should such a decision become necessary. The presiding officer's responsibility to conduct the hearing includes the right and duty to remove a source of substantial disruption. In exercising his or her authority, the presiding officer shall observe the presumption that agency public proceedings are open to

the electronic media. The presiding officer shall exercise his or her discretion to restrict or discontinue electronic coverage of a public proceeding, or portions of a public proceeding, only if he or she determines that the agency's interest in the fair and orderly administrative process is substantially threatened. A clear and substantial threat to the integrity of agency proceedings must clearly outweigh the public interest in electronic media coverage of the proceedings before additional restrictions are imposed on the electronic media during the course of the proceedings. The factors noted in paragraph (e) of this section indicate the kind of substantial threat to the agency interests that may require imposing additional restrictions during the course of the proceedings. If additional requirements are established during the hearing, the presiding officer shall notify immediately the Deputy Commissioner of Food and Drugs of that fact by telephone and submit a written explanation of the circumstances that necessitated such an action within 24 hours or sooner if requested by the Deputy Commissioner. In the absence or unavailability of the Deputy Commissioner, the presiding officer shall notify the Associate Commissioner for Regulatory Affairs.

(h) A decision by a presiding officer, made either before the proceeding or during the course of a proceeding, to establish requirements in addition to the minimum standards set forth in this guideline may be appealed by any adversely affected person who intends to record the proceeding electronically. Appeals may be made in writing or by phone to the Deputy Commissioner or, in his or her absence, to the Associate Commissioner for Regulatory Affairs. The filing of an appeal, whether before or during a proceeding, does not require the presiding officer to interrupt the proceeding. However, the Deputy Commissioner or, in his or her absence, the Associate Commissioner for Regulatory Affairs will resolve an appeal as expeditiously as possible so as to preserve, to the extent possible, the reporters' opportunity to record the proceedings.

[49 FR 14726, Apr. 13, 1984, as amended at 54 FR 9035, Mar. 3, 1989]

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

Subpart A—General Provisions

Subpart B—Electronic Records

Subpart C—Electronic Signatures

AUTHORITY 21 U.S.C. 321–393; 42 U.S.C. 262

SOURCE 62 FR 13464, Mar. 20, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 11.1 Scope.

(a) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(b) This part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations. However, this part does not apply to paper records that are, or have been, transmitted by electronic means.

(c) Where electronic signatures and their associated electronic records meet the requirements of this part, the agency will consider the electronic signatures to be equivalent to full handwritten signatures, initials, and other

presiding officer, to the extent that time permits.

(e) The presiding officer and any other persons serving on a panel may question any person during or at the conclusion of the presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer or panel for response by them or by persons attending the hearing.

(f) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut all such information and views. No participant may interrupt the presentation of another participant at any hearing for any reason.

(g) The hearing may end early only if all persons scheduled for a later presentation have already appeared or it is past the time specified in the hearing schedule, under § 15.21(e), by which participants must be present.

(h) The Commissioner or the presiding officer may, under § 10.19, suspend, modify, or waive any provision of this part.

Subpart C—Records of a Public Hearing Before the Commissioner

§ 15.40 Administrative record.

(a) The administrative record of a public hearing before the Commissioner consists of the following:

(1) All relevant FEDERAL REGISTER notices, including any documents to which they refer.

(2) All written submissions under § 15.25.

(3) The transcript of the oral hearing.

(b) The record of the administrative proceeding will be closed at the time specified in § 15.25.

§ 15.45 Examination of administrative record.

Section 10.20(j) governs the availability for public examination and copying of each document in the administrative record of the hearing

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

Subpart A—General Provisions

Subpart B—Initiation of Proceedings

Subpart C—Commissioner and Presiding Officer

Subpart D—Procedures for Regulatory Hearing

Subpart E—Administrative Record and Decision

Subpart F—Reconsideration and Stay

Subpart G—Judicial Review

AUTHORITY 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364

SOURCE 44 FR 22367, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 16.1 Scope.

The procedures in this part apply when:

(a) The Commissioner is considering any regulatory action, including a refusal to act, and concludes, as a matter of discretion, on the Commissioner's

initiative or at the suggestion of any person, to offer an opportunity for a regulatory hearing to obtain additional information before making a decision or taking action.

(b) The act or a regulation provides a person with an opportunity for a hearing on a regulatory action, including proposed action, and the act or a regulation either specifically provides an opportunity for a regulatory hearing under this part or provides an opportunity for a hearing for which no procedures are specified by regulation. Listed below are the statutory and regulatory provisions under which regulatory hearings are available:

(1) Statutory provisions:

Section 304(g) of the act relating to the administrative detention of devices (see § 800 55(g) of this chapter).

Section 304(h) of the act relating to the administrative detention of food for human or animal consumption (see part 1, subpart k of this chapter).

Section 515(e)(1) of the act relating to the proposed withdrawal of approval of a device premarket approval application.

Section 515(e)(3) of the act relating to the temporary suspension of approval of a premarket approval application.

Section 515(f)(6) of the act relating to a proposed order revoking a device product development protocol or declaring a protocol not completed.

Section 515(f)(7) of the act relating to revocation of a notice of completion of a product development protocol.

Section 516 of the act relating to a proposed banned device regulations (see § 895 21(d) of this chapter).

Section 518(b) of the act relating to a determination that a device is subject to a repair, replacement, or refund order or that a correction plan, or revised correction plan, submitted by a manufacturer, importer, or distributor is inadequate.

Section 518(e) of the act relating to a cease distribution and notification order or mandatory recall order concerning a medical device for human use.

Section 520(f)(2)(D) of the act relating to exemptions or variances from device current good manufacturing practice requirements (see § 820.1(d)).

Section 520(g)(4) and (g)(5) of the act relating to disapproval and withdrawal of approval of an application from an investigational device exemption (see §§ 812.19(c), 812.30(c), 813.30(d), and 813.35(c) of this chapter).

Section 903(a)(8)(B)(ii) of the Federal Food, Drug, and Cosmetic Act relating to the misbranding of tobacco products.

Section 906(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act relating to the establishment of good manufacturing practice requirements for tobacco products.

Section 910(d)(1) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of an order allowing a new tobacco product to be introduced or delivered for introduction into interstate commerce.

Section 911(j) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of an order allowing a modified risk tobacco product to be introduced or delivered for introduction into interstate commerce.

(2) Regulatory provisions:

§ 56.121(a), relating to disqualifying an institutional review board or an institution.

§ 58.204(b), relating to disqualifying a testing facility.

§ 71.37(a), relating to use of food containing a color additive.

§ 80.31(b), relating to refusal to certify a batch of a color additive.

§ 80.34(b), relating to suspension of certification service for a color additive.

§ 99.401(c), relating to a due diligence determination concerning the conduct of studies necessary for a supplemental application for a new use of a drug or device.

§ 130 17(1), relating to a temporary permit to vary from a food standard.

§ 170.17(b), relating to use of food containing an investigational food additive.

§ 202.1(j)(5), relating to approval of prescription drug advertisements.

§ 312 70, relating to whether an investigator is eligible to receive test articles under part 312 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

§ 312.70(d) and 312 44, relating to termination of an IND for a sponsor.

§ 312 160(b), relating to termination of an IND for tests in vitro and in laboratory research animals for a sponsor.

§ 511.1(b)(5), relating to use of food containing an investigational new animal drug.

§ 511.1(c)(1), relating to whether an investigator is eligible to receive test articles under part 511 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

§ 511.1(c) (4) and (d), relating to termination of an INAD for a sponsor.

§ 812 119, relating to whether an investigator is eligible to receive test articles under part 812 of this chapter and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

§ 814 46(c) relating to withdrawal of approval of a device premarket approval application.

§ 822.7(a)(3), relating to an order to conduct postmarket surveillance of a medical device under section 522 of the act.

§ 830 130, relating to suspension or revocation of the accreditation of an issuing agency.

§ 900 7, relating to approval, reapproval, or withdrawal of approval of mammography accreditation bodies or rejection of a proposed fee for accreditation.

§ 900 14, relating to suspension or revocation of a mammography certificate.

§ 900 25, relating to approval or withdrawal of approval of certification agencies.

§ 1003.11(a)(3), relating to the failure of an electronic product to comply with an applicable standard or to a defect in an electronic product.

§ 1003 31(d), relating to denial of an exemption from notification requirements for an electronic product which fails to comply with an applicable standard or has a defect.

§ 1004 6, relating to plan for repurchase, repair, or replacement of an electronic product.

§ 1107.1(d), relating to rescission of an exemption from the requirement of demonstrating substantial equivalence for a tobacco product.

§ 1210 30, relating to denial, suspension, or revocation of a permit under the Federal Import Milk Act.

§ 1270 43(e), relating to the retention, recall, and destruction of human tissue.

§ 1271 440(e) relating to the retention, recall, and destruction of human cells, tissues, and cellular and tissue-based products (HCT/Ps), and/or the cessation of manufacturing HCT/Ps.

[44 FR 22367, Apr. 13, 1979]

EDITORIAL NOTE For FEDERAL REGISTER citations affecting § 16 1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 16.5 Inapplicability and limited applicability.

(a) This part does not apply to the following:

(1) Informal presentation of views before reporting a criminal violation under section 305 of the act and section 5 of the Federal Import Milk Act and § 1210.31.

(2) A hearing on a refusal of admission of a food, drug, device, or cosmetic under section 801(a) of the act and § 1.94, or of an electronic product under section 360(a) of the Public Health Service Act and § 1005.20.

(3) Factory inspections, recalls (except mandatory recalls of medical devices intended for human use), regulatory letters, and similar compliance activities related to law enforcement.

(4) A hearing on an order for relabeling, diversion, or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and §§ 101.17(h) and 115.50 of this chapter.

(5) A hearing on an order for diversion or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264), and § 118.12 of this chapter.

(b) If a regulation provides a person with an opportunity for hearing and specifies some procedures for the hearing but not a comprehensive set of procedures, the procedures in this part apply to the extent that they are supplementary and not in conflict with the other procedures specified for the hearing. Thus, the procedures in subpart A of part 108 relating to emergency permit control are supplemented by the nonconflicting procedures in this part, e.g., the right to counsel, public notice of the hearing, reconsideration and stay, and judicial review.

[44 FR 22367, Apr. 13, 1979, as amended at 57 FR 58403, Dec. 10, 1992; 65 FR 76110, Dec. 5, 2000; 74 FR 33095, July 9, 2009]

Subpart B—Initiation of Proceedings

§ 16.22 Initiation of regulatory hearing.

(a) A regulatory hearing is initiated by a notice of opportunity for hearing from FDA. The notice will—

(1) Be sent by mail, telegram, telex, personal delivery, or any other mode of written communication;

(2) Specify the facts and the action that are the subject of the opportunity for a hearing;

(3) State that the notice of opportunity for hearing and the hearing are governed by this part; and

(4) State the time within which a hearing may be requested, and state the name, address, and telephone number of the FDA employee to whom any request for hearing is to be addressed.

(5) Refer to FDA's guideline on electronic media coverage of its administrative proceedings (21 CFR part 10, subpart C).

(b) A person offered an opportunity for a hearing has the amount of time specified in the notice, which may not be less than 3 working days after receipt of the notice, within which to request a hearing. The request may be filed by mail, telegram, telex, personal delivery, or any other mode of written communication, addressed to the designated FDA employee. If no response is filed within that time, the offer is deemed to have been refused and no hearing will be held.

(c) If a hearing is requested, the Commissioner will designate a presiding officer, and the hearing will take place at a time and location agreed upon by the party requesting the hearing, the FDA, and the presiding officer or, if agreement cannot be reached, at a reasonable time and location designated by the presiding officer.

(d) A notice of opportunity for hearing under this section will not operate to delay or stay any administrative action, including enforcement action by the agency unless the Commissioner, as a matter of discretion, determines that delay or a stay is in the public interest.

[44 FR 22367, Apr. 13, 1979, as amended at 49 FR 32173, Aug. 13, 1984]

§ 16.24 Regulatory hearing required by the act or a regulation.

(a) A regulatory hearing required by the act or a regulation under § 16.1(b) will be initiated in the same manner as other regulatory hearings subject to the additional procedures in this section.

(b) [Reserved]

(c) The notice will state whether any action concerning the matter that is the subject of the opportunity for hearing is or is not being taken pending the hearing under paragraph (d) of this section.

(d) The Commissioner may take such action pending a hearing under this section as the Commissioner concludes is necessary to protect the public health, except where expressly prohibited by statute or regulation. A hearing to consider action already taken, and not stayed by the Commissioner, will be conducted on an expedited basis.

(e) The hearing may not be required to be held at a time less than 2 working days after receipt of the request for hearing.

(f) Before the hearing, FDA will give to the party requesting the hearing reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the decision or action taken or proposed that is the subject of the hearing and a general summary of the information that will be presented by FDA at the hearing in support of the decision or action. This information may be given orally or in writing, in the discretion of FDA.

(g) FDA and the party requesting the hearing will, if feasible, at least 1 day before the hearing provide to each other written notice of any published articles or written information to be presented at or relied on at the hearing. A copy will also be provided in advance if the other participant could not reasonably be expected to have or be able to obtain a copy. If written notice or a copy is not provided, the presiding officer may, if time permits, allow the party who did not receive the notice or copy additional time after the close of the hearing to make a submission concerning the article or information.

[44 FR 22367, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982; 54 FR 9037, Mar. 3, 1989]

§ 16.26 Denial of hearing and summary decision.

(a) A request for a hearing may be denied, in whole or in part, if the Commissioner or the FDA official to whom

authority is delegated to make the final decision on the matter determines that no genuine and substantial issue of fact has been raised by the material submitted. If the Commissioner or his or her delegate determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(b) After a hearing commences, the presiding officer may issue a summary decision on any issue in the hearing if the presiding officer determines from the material submitted in connection with the hearing, or from matters officially noticed, that there is no genuine and substantial issue of fact respecting that issue. For the purpose of this paragraph, a hearing commences upon the receipt by FDA of a request for hearing submitted under § 16.22(b).

(c) The Commissioner or his or her delegate may review any summary decision of the presiding officer issued under paragraph (b) of this section at the request of a party or on the Commissioner's or his or her delegate's own initiative.

[53 FR 4615, Feb. 17, 1988, as amended at 69 FR 17290, Apr. 2, 2004]

Subpart C—Commissioner and Presiding Officer

§ 16.40 Commissioner.

Whenever the Commissioner has delegated authority on a matter for which a regulatory hearing is available under this part, the functions of the Commissioner under this part may be performed by any of the officials to whom the authority has been delegated, e.g., a center director.

[69 FR 17290, Apr. 2, 2004]

§ 16.42 Presiding officer.

(a) An FDA employee to whom the Commissioner delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, or, consistent with 5 CFR 930.209(b) or (c), an administrative law judge to whom such authority is delegated, may serve as the presiding officer and conduct a regulatory hearing under this part.

(b) In a regulatory hearing required by the act or a regulation, the presiding officer is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action.

(c)(1) The Commissioner or the delegate under § 16.40 is not precluded by this section from prior participation in the investigation or action that is the subject of the hearing. If there has been prior participation, the Commissioner or the delegate should, if feasible, designate a presiding officer for the hearing who is not a subordinate. Thus, if the Commissioner's authority to make a final decision has been delegated to a center director, the presiding officer may be an official in another center or the office of the Commissioner. The exercise of general supervisory responsibility, or the designation of the presiding officer, does not constitute prior participation in the investigation or action that is the subject of the hearing so as to preclude the Commissioner or delegate from designating a subordinate as the presiding officer.

(2) The party requesting a hearing may make a written request to have the Commissioner or the delegate under § 16.40 be the presiding officer, notwithstanding paragraph (c)(1) of this section. If accepted, as a matter of discretion, by the Commissioner or the delegate, the request is binding upon the party making the request.

(3) A different presiding officer may be substituted for the one originally designated under § 16.22 without notice to the parties.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989; 67 FR 53306, Aug. 15, 2002]

§ 16.44 Communication to presiding officer and Commissioner.

(a) Regulatory hearings are not subject to the separation of functions rules in § 10.55.

(b) Those persons who are directly involved in the investigation or presentation of the position of FDA or any party at a regulatory hearing that is required by the act or a regulation

should avoid any off-the-record communication on the matter to the presiding officer or the Commissioner or their advisors if the communication is inconsistent with the requirement of § 16.95(b)(1) that the administrative record be the exclusive record for decision. If any communication of this type occurs, it is to be reduced to writing and made part of the record, and the other party provided an opportunity to respond.

(c) A copy of any letter or memorandum of meeting between a participant in the hearing and the presiding officer or the Commissioner, e.g., a response by the presiding officer to a request for a change in the time of the hearing, is to be sent to all participants by the person writing the letter or the memorandum.

Subpart D—Procedures for Regulatory Hearing

§ 16.60 Hearing procedure.

(a) A regulatory hearing is public, except when the Commissioner determines that all or part of a hearing should be closed to prevent a clearly unwarranted invasion of personal privacy; to prevent the disclosure of a trade secret or confidential commercial or financial information that is not available for public disclosure under § 20.61; or to protect investigatory records complied for law enforcement purposes that are not available for public disclosure under § 20.64.

(1) The Commissioner may determine that a regulatory hearing is closed either on the Commissioner's initiative or on a request by the party asking for a regulatory hearing, in the request for the hearing.

(2) If the hearing is a private hearing, no persons other than the party requesting the hearing, counsel and witnesses, and an employee or consultant or other person subject to a commercial arrangement as defined in § 20.81(a) and FDA representatives with a direct professional interest in the subject matter of the proceeding are entitled to attend.

(b) A regulatory hearing will be conducted by a presiding officer. Employees of FDA will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present any oral or written information relevant to the hearing. The party requesting the hearing may then present any oral or written information relevant to the hearing. All parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(c) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any other party may comment upon or rebut all such data, information, and views.

(d) The presiding officer may order the hearing to be transcribed. The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to FDA. Any transcript of the hearing will be included with the presiding officer's report of the hearing.

(e) The presiding officer shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the parties to the hearing will be given the opportunity to review and comment on the presiding officer's report of the hearing.

(f) The presiding officer shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons, unless the Commissioner directs otherwise.

(g) The presiding officer has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct a fair, expeditious, and impartial hearing, and to enforce the requirements of this part concerning the conduct of hearings. The presiding officer may direct that the hearing be conducted in any suitable manner permitted by law and these regulations.

(h) The Commissioner or the presiding officer has the power under § 10.19 to suspend, modify, or waive any provision of this part.

[44 FR 22367, Apr. 13, 1979, as amended at 66 FR 6469, Jan. 22, 2001; 66 FR 12850, Mar. 1, 2001]

§ 16.62 Right to counsel.

Any party to a hearing under this part has the right at all times to be advised and accompanied by counsel.

Subpart E—Administrative Record and Decision

§ 16.80 Administrative record of a regulatory hearing.

(a) The administrative record of the regulatory hearing consists of the following:

(1) The notice of opportunity for hearing and the response.

(2) All written information and views submitted to the presiding officer at the hearing or after if specifically permitted by the presiding officer.

(3) Any transcript of the hearing.

(4) The presiding officer's report of the hearing and comments on the report under § 16.60(e).

(5) All letters and memoranda of meetings or communications between participants and the presiding officer or the Commissioner referred to in § 16.44(c).

(b) The record of the regulatory hearing is closed to the submission of information and views, at the close of the hearing, unless the presiding officer specifically permits additional time for a further submission.

§ 16.85 Examination of administrative record.

Part 20 governs the availability for public disclosure of each document that is a part of the administrative record of a regulatory hearing.

§ 16.95 Administrative decision and record for decision.

(a) With respect to a regulatory hearing at the Commissioner's initiative under § 16.1(a), the Commissioner shall consider the administrative record of the hearing specified in § 16.80(a) together with all other relevant information and views available to FDA in determining whether regulatory action should be taken and, if so, in what form.

(b) With respect to a regulatory hearing required by the act or a regulation under § 16.1(b)—

(1) The administrative record of the hearing specified in § 16.80(a) constitutes the exclusive record for decision;

(2) On the basis of the administrative record of the hearing, the Commissioner shall issue a written decision stating the reasons for the Commissioner's administrative action and the basis in the record; and

(3) For purposes of judicial review under § 10.45, the record of the administrative proceeding consists of the record of the hearing and the Commissioner's decision.

Subpart F—Reconsideration and Stay

§ 16.119 Reconsideration and stay of action.

After any final administrative action that is the subject of a hearing under this part, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.35.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

Subpart G—Judicial Review

§ 16.120 Judicial review.

Section 10.45 governs the availability of judicial review concerning any regulatory action which is the subject of a hearing under this part

PART 17—CIVIL MONEY PENALTIES HEARINGS

Sec.

(c) *Final report.* An investigator shall provide the sponsor with an adequate report shortly after completion of the investigator's participation in the investigation.

(d) *Financial disclosure reports.* The clinical investigator shall provide the sponsor with sufficient accurate financial information to allow an applicant to submit complete and accurate certification or disclosure statements as required under part 54 of this chapter. The clinical investigator shall promptly update this information if any relevant changes occur during the course of the investigation and for 1 year following the completion of the study.

[52 FR 8831, Mar. 19, 1987, as amended at 52 FR 23031, June 17, 1987; 63 FR 5252, Feb. 2, 1998; 67 FR 9586, Mar. 4, 2002; 75 FR 59963, Sept. 29, 2010]

§ 312.66 Assurance of IRB review.

An investigator shall assure that an IRB that complies with the requirements set forth in part 56 will be responsible for the initial and continuing review and approval of the proposed clinical study. The investigator shall also assure that he or she will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risk to human subjects or others, and that he or she will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

[52 FR 8831, Mar. 19, 1987, as amended at 52 FR 23031, June 17, 1987; 67 FR 9586, Mar. 4, 2002]

§ 312.68 Inspection of investigator's records and reports.

An investigator shall upon request from any properly authorized officer or employee of FDA, at reasonable times, permit such officer or employee to have access to, and copy and verify any records or reports made by the investigator pursuant to § 312.62. The investigator is not required to divulge subject names unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual case studies, or do not represent actual results obtained.

§ 312.69 Handling of controlled substances.

If the investigational drug is subject to the Controlled Substances Act, the investigator shall take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

§ 312.70 Disqualification of a clinical investigator.

(a) If FDA has information indicating that an investigator (including a sponsor-investigator) has repeatedly or deliberately failed to comply with the requirements of this part, part 50 or part 56 of this chapter, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research will furnish the investigator written notice of the matter complained of and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. If an explanation is offered and accepted by the applicable Center, the Center will discontinue the disqualification proceeding. If an explanation is offered but not accepted by the applicable Center, the investigator will be given an opportunity for a regulatory hearing under part 16 of this chapter on the question of whether the investigator is eligible to receive test articles under this part and eligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA.

(b) After evaluating all available information, including any explanation presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50 or part 56 of this chapter, or has repeatedly or deliberately submitted to FDA or to the sponsor false information in any required report, the Commissioner will notify the investigator, the sponsor of

any investigation in which the investigator has been named as a participant, and the reviewing institutional review boards (IRBs) that the investigator is not eligible to receive test articles under this part. The notification to the investigator, sponsor, and IRBs will provide a statement of the basis for such determination. The notification also will explain that an investigator determined to be ineligible to receive test articles under this part will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, including drugs, biologics, devices, new animal drugs, foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, and tobacco products.

(c) Each application or submission to FDA under the provisions of this chapter containing data reported by an investigator who has been determined to be ineligible to receive FDA-regulated test articles is subject to examination to determine whether the investigator has submitted unreliable data that are essential to the continuation of an investigation or essential to the approval of a marketing application, or essential to the continued marketing of an FDA-regulated product.

(d) 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 the sponsor, who shall have an opportunity for a regulatory hearing under part 16 of this chapter. If a danger to the public health exists, however, the Commissioner shall terminate the IND immediately and notify the sponsor and the reviewing IRBs of the termination. In such case, the sponsor shall have an opportunity for a regulatory hearing before FDA under part 16 on the question of whether the IND should be reinstated. The determination that an investigation may not be considered in support of a research or marketing application or a notification or petition submission does not, however, relieve the sponsor of any obligation under any other applicable regulation to submit to FDA the results of the investigation.

(e) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the continued approval of the product for which the data were submitted cannot be justified, the Commissioner will proceed to withdraw approval of the product in accordance with the applicable provisions of the relevant statutes.

(f) An investigator who has been determined to be ineligible under paragraph (b) of this section may be reinstated as eligible when the Commissioner determines that the investigator has presented 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 the applicable provisions of this chapter.

[77 FR 25359, Apr. 30, 2012]

Subpart E—Drugs Intended to Treat Life-threatening and Severely-debilitating Illnesses

AUTHORITY 21 U.S.C. 351, 352, 353, 355, 371; 42 U.S.C. 262.

SOURCE 53 FR 41523, Oct. 21, 1988, unless otherwise noted.

§ 312.80 Purpose.

The purpose of this section is to establish procedures designed to expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening and severely-debilitating illnesses, especially where no satisfactory alternative therapy exists. As stated § 314.105(c) of this chapter, while the statutory standards of safety and effectiveness apply to all drugs, the many kinds of drugs that are subject to them, and the wide range of uses for those drugs, demand flexibility in applying the standards. The Food and Drug Administration (FDA) has determined that it is appropriate to exercise the broadest flexibility in applying the statutory standards, while preserving appropriate guarantees for safety and