SMG 7711.1

FDA STAFF MANUAL GUIDES, VOLUME IV – AGENCY PROGRAM DIRECTIVES

COMPLIANCE ACTIVITIES

MAINTAINING AND CONTROLLING PART 16 REGULATORY HEARING ADMINISTRATIVE RECORDS FOR INVESTIGATOR DISQUALIFICATION MATTERS

Effective Date: 02/25/2011
Changed: 08/08/2023

1. PURPOSE

This Staff Manual Guide (SMG) sets forth policy and responsibilities for the location, maintenance, control, and disposition of administrative records pertaining to 21 CFR Part 16 (Part 16) hearings for clinical investigator disqualification matters.[1] The responsibilities and procedures described in this SMG refer to Part 16 regulatory hearing administrative records maintained and controlled for investigator disqualification matters only.

2. BACKGROUND

Between 1999 and 2008, the FDA Office of the Ombudsman was responsible for maintaining and controlling administrative records pertaining to all Part 16 regulatory hearings. In 2008, the Office of Good Clinical Practice in the Office of the Commissioner assumed responsibility for coordinating investigator disqualification

[1] A Part 16 regulatory hearing, including a hearing that pertains to an investigator disqualification matter, is initiated by a Notice of Opportunity for Hearing (NOOH) from FDA (21 CFR 16.22). The person offered an opportunity for a hearing has the amount of time specified in the NOOH within which to request the hearing. Pursuant to 21 CFR 16.26, a request for a hearing may be denied, in whole or in part, if the Commissioner or her delegate determines that no genuine and substantial issue of fact had been raised by the material submitted. The issuance of a Commissioner's Decision or a Notice of Denial of Hearing and Disqualification of Eligibility to Receive Investigational Product is considered final agency action in disqualification matters.

matters and for maintaining and controlling Part 16 regulatory hearing records associated with such matters.

Because of program and organizational changes, the March 25, 1988, SMG 3291.6, "Maintaining and Controlling Part 16 Regulatory Hearing Files", was retired from the FDA Intranet on July 15, 2009. This SMG supersedes in part the 1988 SMG 3291.6. Certain relevant policies and responsibilities described in the 1988 SMG 3291.6 are incorporated into this SMG. In addition, some of the policies and responsibilities described in the 1988 SMG 3291.6 are now covered by the records retention schedules found in the FDA Records Control Schedules.[2]

3. DEFINITIONS

A. Administrative File. The file or files containing all agency documents pertaining to a particular administrative action, including internal working memoranda, and recommendations (21 CFR 10.3; see also 21 CFR 10.70 – Documentation of significant decisions in administrative file).

B. Administrative Record. The documents in the administrative file of a particular administrative action on which the Commissioner relies to support the action (21 CFR 10.3). Under 21 CFR 16.80(a), the administrative record for Part 16 regulatory hearings consists of the following:

1. The Notice of Opportunity for Hearing (NOOH) and the response.

2. All written information and views submitted to the presiding officer at the hearing or after, if the submission is 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 submitted under 21 CFR 16.60(e).

5. All letters and memoranda of meetings or communications between participants and the presiding officer or the Commissioner referred to in 21 CFR 16.44(c).

C. Federal Docket. The Federal Docket, among other functions, provides the documentation of the final action in an investigator disqualification proceeding conducted under a Part 16 regulatory hearing process. The posting of these final actions in the Docket facilitates public access to possible precedent-setting documents (e.g., Presiding Officer Reports and Commissioner's Decisions). The Federal Docket is located at the Regulations.gov web site (www.regulations.gov).

[2] See https://fda.sharepoint.com/sites/OC-Intranet-OC-OO-OEMS-DIG-Records-Management-Team/SitePages/Introduction--FDA-Records-Control-Schedules.aspx

D. Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE). A NIDPOE informs the recipient investigator that FDA is initiating an administrative proceeding to determine whether the clinical investigator should be disqualified from receiving investigational articles pursuant to FDA's regulations. FDA issues a NIDPOE when FDA has evidence that the clinical investigator repeatedly or deliberately violated FDA's regulations governing the proper conduct of clinical studies involving investigational articles or repeatedly or deliberately submitted false information to FDA or to the sponsor in any required report.

E. Notice of Opportunity for Hearing (NOOH). A regulatory hearing is initiated by a NOOH from FDA (21 CFR 16.22). Among other requirements, the NOOH must "[s]pecify the facts and the action that are the subject of the opportunity for a hearing" (21 CFR 16.22(a)(2)).

F. Project Manager. The Project Manager is a staff member in the Office of Good Clinical Practice and is assigned certain responsibilities when an investigator requests a Part 16 hearing, and during the Part 16 regulatory hearing process for investigator disqualification matters. These responsibilities are outlined in SMG 7711 – "Disqualification of a Clinical Investigator: The Hearing Process".

4. POLICY

Administrative records are maintained and controlled in accordance with relevant statutes, regulations, FDA policy, and FDA's Records Control Schedules. Certain administrative records are kept permanently for precedential purposes.[3] Administrative records that pertain to a Part 16 regulatory hearing proceeding, including final action concerning an investigator disqualification matter, are precedential documents. Therefore, when possible, FDA intends to permanently keep administrative records of Part 16 regulatory hearing proceedings in investigator disqualification matters.[4]

5. RESPONSIBILITIES

A. Office of Good Clinical Practice

- The Project Manager in the Office of Good Clinical Practice is responsible for maintaining and controlling Part 16 regulatory hearing administrative records for investigator disqualification matters under 21 CFR 312.70, 511.1(c), and

[3] See, for example, the HHS, Office of General Counsel, Legal Opinion Precedent File Records Control Schedule.

[4] When possible, FDA keeps those records rather than transferring them to the National Archives and Records Administration (NARA) because NARA considers those records to be temporary. NARA deletes or destroys records it considers temporary 75 years after the end of the fiscal year after the final action or when no longer needed for administrative, legal, or reference purposes, whichever is the latest.

812.119, from the initiation of the hearing process (i.e., when the NOOH is issued (21 CFR 16.22(a)) to a final agency action. These records of an ongoing disqualification process are located in the Office of Good Clinical Practice files. However, if the initiating Office or Center reaches a settlement that obviates the need for a Part 16 hearing, the Office or Center will be responsible for maintaining the administrative record (see section B below).

- The Project Manager in the Office of Good Clinical Practice is responsible for the disposition of the administrative records in investigator disqualification matters in which there is a final agency action resulting in investigator disqualification, for example, a Commissioner's Decision. For such matters, the Project Manager will arrange for the safekeeping of the records in the Office of Good Clinical Practice, or the transfer of the records to another FDA component[5] or to NARA if necessary.[6]

B. Initiating Office or Center

The Office or Center that initiates the disqualification matter, by issuing a NIDPOE, is responsible for the following:

- Notifying the Project Manager in the Office of Good Clinical Practice when the NIDPOE and NOOH are issued.

- Ensuring NIDPOEs and NOOHs are redacted and posted in FDA's website http://www.fda.gov/disqualificationproceedings.

- Preparing and maintaining the formal administrative record in accordance with the FDA Records Control Schedules when the initiating Office or Center reaches a settlement that obviates the need for a Part 16 hearing. Such a settlement may be reached either before or after issuance of a NOOH.

- Notifying the Project Manager in the Office of Good Clinical Practice when such a settlement is reached through a consent agreement or otherwise.

6. PROCEDURES

A. Office of Good Clinical Practice

[5] For example, the records may be transferred to the Division of Dockets Management, Office of Management and Operations, FDA, U.S. Department of Health and Human Services. When records are transferred to the Division of Dockets Management, records are placed in a Docket, and arranged by year under a Docket control number.

[6] As explained in footnote 4, when possible, FDA intends to keep the records for investigator disqualification matters in which there is a final agency action because NARA considers those records to be temporary and may destroy or delete them after 75 years.

1. The Project Manager in the Office of Good Clinical Practice assembles the formal administrative record in investigator disqualification matters in which there is a final agency action after a Part 16 regulatory hearing. The Project Manager typically begins to assemble the record when the disqualification matter is initiated. The administrative record includes, but is not limited to, the following documents if available:

   a. items listed in 21 CFR 16.80(a),

   b. the Presiding Officer's Report, and

   c. Commissioner's Decision.

2. The Project Manager files, and arranges for the permanent maintenance of, the administrative record of any investigator disqualification matter in which a Part 16 regulatory hearing is held.

3. The Project Manager sends to the initiating Office or Center, to retain as needed in accordance with internal office procedures, a copy of the record of any investigator disqualification matter in which a Part 16 regulatory hearing is held.

4. When a Commissioner's Decision is issued, the Project Manager ensures that the Commissioner's Decision and other relevant associated documents (e.g., the cover letter and Presiding Officer's Report) are redacted[7] and posted on the Internet at http://www.fda.gov/disqualificationproceedings.

5. After redaction, the Project Manager asks the Division of Dockets Management[8] to assign a Docket number (if not already assigned) and post the redacted document(s) in the Federal Docket.[9]

6. If there is judicial review of the agency action or if the Office of the Chief Counsel (OCC) requests it, the Project Manager will send OCC the administrative record.

B. Initiating Office or Center

1. The initiating Office or Center maintains and disposes of copies of the administrative record for a Part 16 regulatory hearing that pertains to an investigator disqualification proceeding according to the initiating Office's or

[7] For a description of the responsibilities concerning this procedure, see SMG 7711 – "Disqualification of a Clinical Investigator: The Hearing Process", at https://www.fda.gov/media/80788/download.
[8] See https://www.fda.gov/regulatory-information/dockets-management.
[9] See http://www.regulations.gov.

Center's internal procedures, FDA's Records Control Schedules, and current law.

2. If the initiating Office or Center reaches a settlement before issuing a NOOH, the initiating Office or Center maintains the formal administrative record in accordance with the FDA Records Control Schedules, and current law.

3. If the investigator is disqualified through a Commissioner's Decision after a Part 16 regulatory hearing (or through a Notice of Denial of Hearing and Disqualification of Eligibility to Receive Investigational Articles, or a consent agreement), the initiating Center will forward information about the investigator's disqualification to the Director, Division of Enforcement (ORA) so that the investigator's name can be included on the list of disqualified investigators on FDA's web site at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/clinical-investigators-disqualification-proceedings. [10]

C. Office of the Chief Counsel

In the event of judicial review of the agency action, the Office of the Chief Counsel may retain the administrative record, or request it from the Project Manager in the Office of Good Clinical Practice.

D. Other Affected Offices

If an Office affected by the matter needs all or part of the administrative record of a particular disqualification matter for program purposes, that Office will maintain a copy of the administrative record needed. The affected Office will maintain and dispose of the administrative record in accordance with that Office's internal procedures, FDA's Records Control Schedules, and current law.

7. EFFECTIVE DATE

This guide is effective immediately.

[10] For a description of the responsibilities concerning this procedure, see SMG 7711 (*id.* at footnote 7).

8. History – SMG 7711.1, Maintaining and Controlling Part 16 Regulatory Hearing Administrative Records for Investigator Disqualification Matters

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	02/25/2011	N/a	Kathleen Pfaender, Senior Health Policy Analyst, Office of Good Clinical Practice (OGCP), Office of the Commissioner	Joanne Less, Director, OGCP, Office of the Commissioner
Change	08/06/2013	Sect. 5.B. second bullet; Sect. 6.A.4. URL; Sect. 6.B.3. URL and Division title; Sect. 6.D. first sentence	Kathleen Pfaender, Senior Health Policy Analyst, Office of Good Clinical Practice (OGCP), Office of the Commissioner	Kathleen Pfaender, Senior Health Policy Analyst, Office of Good Clinical Practice (OGCP), Office of the Commissioner
Change	02/20/2015	Footnote 7 hyperlink	Office of Good Clinical Practice (OGCP), Office of the Commissioner	Joanne Less, Director, OGCP, Office of the Commissioner
Change	11/25/2019	Footnotes 7 and 8 URLs; Sect. 6.B.3. URL	Office of Good Clinical Practice (OGCP), Office of the Commissioner	Joanne Less, Director, OGCP, Office of the Commissioner
Change	08/02/2023	Footnote 2 URL	OC/OCPP/OCP	Ann Meeker-O'Connell, Director, OC/OCPP/OCP