1. PURPOSE

This staff manual guide (SMG) outlines FDA’s internal policy and procedures for requesting records and other information in advance of or in lieu of an inspection related to human or animal drugs, including human biological drug products, under authority of section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 374(a)). Section 704(a)(4) of the FD&C Act requires “a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug” to provide FDA, upon request, records or other information that FDA may inspect under section 704(a)(4). Under the statutory authority, upon receipt of the requested records, FDA must provide the establishment with confirmation of receipt.

The SMG is intended to align the record request process across FDA components and to foster clear expectations for FDA Centers and ORA staff. The use of this authority will help improve the overall effectiveness of the drug inspection program. The records received from an establishment may be

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1 To access the fillable Records Request (Form FDA 4003) and Receipt Confirmation (Form FDA 4003a) templates, see the “Attachments” pane in the Adobe Acrobat .pdf viewer. FDA staff may also access them on the internal Forms intranet site, at http://inside.fda.gov:9003/Administrative/Forms/FDA/ORA/default.htm.

2 Center for Drug Evaluation and Research (CDER), Center for Veterinary Medicine (CVM), Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs (ORA) are involved in drug inspections.
used to inform inspection planning, prepare for a scheduled inspection, inform FDA’s decision to adjust the interval between on-site inspections (e.g., surveillance), or use the records in lieu of certain inspections.

When planning programs for using section 704(a) authority, individual Center and ORA offices and sub-offices are expected to develop and follow more detailed internal procedures that follow policy and procedures described in this cross-Center SMG as guiding principles.

This SMG is not intended to limit the authority or ability of the FDA Centers or ORA staff to carry out their duties under other provisions of applicable laws and regulations. FDA does not expect all inspection-related communications with drug establishments to be issued as record requests under section 704(a)(4) of the FD&C Act. For example, existing policy covering post-inspection requests made to a drug establishment or covering requests for information related to a recall remains in effect. Furthermore, the scope of this SMG does not impact what documents may be reasonably requested during an on-site inspection. During an inspection, FDA may collect copies of previously received documents and other documents not previously requested or received.

This SMG is not intended to limit or curtail other routine communications that FDA Centers and ORA staff may have with drug establishments under authorities or communication processes that exist apart from section 704(a)(4) of the FD&C Act, such as requests for documents in the course of application submission reviews.

This SMG replaces previous SMG 9004.1 (Nov. 2014), which outlined procedures for the use of section 704(a)(4) specifically in the event of a public health incident related to drugs. See Policy section for specific information related to public health incidents.

2. POLICY

The SMG establishes the following policies, which are further described in Responsibilities and Procedures Section below:

- Each request by Centers and ORA staff must describe the statutory authority used and include a statement addressing the refusal to provide records (see Sec. 3.B.1.ii).

- Centers and ORA staff should refer to this SMG as a procedural guide in order to ensure that requests are made in a reasonable manner.

- Centers and ORA staff should ask that each establishment respond to the request within 15 calendar days, or 30 calendar days when language
translation of records is requested. The FD&C Act requires that records requested be provided to FDA in a reasonable timeframe.

- Centers and ORA staff should check the resources readily available to them for past or current record requests made under section 704(a)(4) authority to the same establishment to avoid duplication, when possible.

- Centers and ORA staff may elect to follow this SMG to obtain records in the event of a public health incident related to human or animal drugs, including the potential for such an event. If so elected, such use may be used in addition to or instead of other existing processes FDA offices have in place for obtaining information in the event of a public health incident. For the purposes of this SMG, a public health incident related to human or animal drugs is defined as an occurrence, or combination of circumstances, that poses a significant risk to public health that involves the safety, efficacy, or security of a human or animal drug and calls for action by FDA staff.³

3. RESPONSIBILITIES AND PROCEDURES

According to section 704(a)(4), the records requested must be provided within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and as either electronic or paper copies. In its request, FDA staff must include a sufficient description of the records requested. Upon receipt of the records requested, FDA shall provide a confirmation of receipt.

The Center or Office may request the records in accordance with the Center/Office’s own procedures, subject to the common instructions described below.

A. Timeframe between Request and Receipt

Centers and ORA staff should ensure that the 15 calendar days/30 calendar days reasonable timeframe policy is followed and that time is allowed for receipt and review of the records prior to the start of any planned inspection.

There may be circumstances in which a records request necessitates a shorter or a longer response timeframe. Changes in inspection planning, scheduling, or preparation priorities may justify such circumstances.

³ FDA may learn of a potential or actual public health incident from many sources, including information developed internally by FDA or from outside entities, such as states or other domestic or foreign agencies. When FDA learns of such information, the appropriate Center or Office generally will assess whether a public health incident related to human or animal drugs, or the potential for such an event, exists and whether the Agency should request records in advance of or in lieu of an inspection. If so, then staff should follow the procedures in this SMG along with accompanying Center- or Office-level procedures.
Centers and ORA staff should explain the rationale for their preferred timeframe in internal procedures and communicate with the establishment, as necessary, to ensure that requested timeframes are reasonable and can be met.

In the event of a public health incident, given the nature of the incident, it is reasonable that the response timeframes may be shorter. FDA should work with the establishment to ensure that shorter timeframes can be satisfied.

B. Form of Request

1. Centers and ORA staff should ensure that each records request made pursuant to section 704(a)(4) includes, at a minimum:

   a. The following statement, which provides notice to the regulated establishment that FDA is exercising the statutory authority in making the request: “Under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(a)(4)], FDA requests that you provide the records described below. If the records requested do not exist, please state that fact in your response.”

   b. The following statement, which provides a general description to the regulated establishment of consequences for refusal to provide requested records within the specified timeframe: “Failure to submit records requested under section 704(a) may cause your product to be adulterated within the meaning of section 501(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act [21 U.S.C. 351(j)]).”

   Attachment A contains a records request template that should be used.

2. A sufficient description of the records sought by FDA.

   a. The records requested must be records that the Secretary may inspect under section 704(a). Records of particular batches as well as product-specific information, such as annual product reviews or product quality reports may be requested. FDA may also reasonably request establishments to provide certain records to facilitate and expedite FDA’s review, such as summaries of other records. For example, FDA may request such information commonly reviewed during an on-site inspection such as a list of all drugs manufactured at a facility, a summary of batches manufactured and their disposition, a summary of discrepancies and investigations related to manufacturing and testing, and the like. Furthermore, FDA may routinely request and receive electronic
databases or summary data generated by the firm from their databases.\textsuperscript{4}

In such cases, FDA should include a brief statement explaining that such summary information is meant to expedite FDA review and is typically reviewed during on-site inspections. It is appropriate to ask for such summaries or translations to be created, in the same way that such a request might be made during an inspection. It is appropriate to ask that, if the firm does not provide records because they do not currently exist, that it attest to that fact. In some cases, the lack of such records may violate current good manufacturing practices, see, e.g. 21 CFR 211.180.

Centers and ORA staff may request other information per office-level procedures, according to their programs’ needs.

b. Along with the particular documents sought for review, Center and ORA staff may also choose to request that the establishment provide an accompanying statement, certified and signed by the establishment’s most responsible person, stating that the information provided is accurate and reliable.

c. It is important to note that some establishments may not use the terms familiar to FDA staff when naming or referencing records in response to an FDA request. FDA staff should strive to use clear, generally understood terminology when requesting documents, and to communicate clearly with establishments requiring further clarification.

d. A reasonable request for records should limit the timespan covered by the request. It is important for all Centers and ORA staff to consider requesting information generated by the establishment more recently than the last inspection as well as other reasonable timespans within the record retention requirement.

e. Centers and ORA staff may reasonably request that records be in English or accompanied by an English translation. If translated, the records translation should be verified to be complete and accurate, and include the name, address, and a brief statement of the qualifications of the translator. Copies of the original records should also be included in the response.

\textsuperscript{4} In requesting such information from databases, FDA investigators follow the procedures described in the Investigations Operations Manual (IOM) 5.3.8.3.2 – Electronic Databases and Queries, \url{https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf} at p. 266.
By requesting that records be provided in English, FDA hopes to minimize the time needed for review. If a verified translation is not immediately available, FDA may request that the initial translation be followed up with a verified translation as soon as practicable.

3. The method for submitting a response with the requested records.

Centers and ORA staff should request that records be sent by electronic means when possible, that is, via electronic mail. If FDA or the establishment has concerns about the security of sending documents via electronic mail, FDA staff may advise the establishment to consider contacting SecureEmail@fda.hhs.gov to obtain a license to send encrypted messages to FDA via electronic mail. FDA encourages the establishment to provide electronic responses. However, if this is not feasible, responses consisting of paper records are also acceptable.

Individual offices may choose to use a shared email account to request and receive records and send the confirmation of receipt; procedures associated with the use of such an account should be described in office-level procedures.

4. The name and contact information of the FDA staff member responsible for the records request.

By providing an FDA contact, the establishment may efficiently seek a response to any questions or concerns about the records request.

C. Action If Records Not Provided

As noted in 3.B.1.ii above, each request should include a statement worded in the manner stated in 3.B.1.ii, that a failure to provide records requested under section 704(a)(4) may result in products produced at the establishment to be deemed adulterated under section 501(j) of the FD&C Act. In general, the Agency considers the scope of records it may inspect under section 704(a) of the FD&C Act to include all records maintained by the establishment that are not specifically exempt under that section. However, not all information that FDA may inspect under section 704(a) is

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5 Section 704(a) of the FD&C Act allows for inspection of all records except for those containing “financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to [the FD&C] Act), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 519, section 520(g) or chapter IX and data relating to other drugs, devices or tobacco products which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(jj))."
routinely maintained by all establishments under current Good Manufacturing Practice and other applicable regulations.

Therefore, a refusal to provide requested documents should be reviewed on a case-by-case basis first with compliance management within individual Centers, and with Agency legal counsel, to consider further action.

D. Confirmation of Receipt of Records

The confirmation of receipt should include, at a minimum:

1. Language indicating that the confirmation “constitutes a confirmation of receipt of records requested under FD&C Act section 704(a)(4).”

2. Language indicating that the confirmation affirms only that the FDA has received the records but not that the records are complete, accurate, responsive, or otherwise satisfy the request.

3. The address, firm name, and point of contact at the firm who responded to the request. This information may or may not be the same as the individual or establishment that submitted the records.

4. Identification of the FDA Center or Office sending the confirmation.

5. Method by which the records were transmitted to the FDA.

6. Date the records were received by the FDA.

When records that have been the subject of a single request arrive at FDA, in a staggered manner, such as on different days, the requester may opt to confirm receipt after the final record has been received or confirm the receipt of the records and information as they arrive.

Attachment B contains a receipt confirmation template, which should be used.

E. Central Repository for Requests, Receipts, and Records Received

The requesting Center or Office will be responsible for maintaining the requests for records made, the firm’s responses, and the record receipt, initiated under section 704(a)(4). A copy of each request should be uploaded into the Compliance Management System (CMS). Uploaded requests are entered into CMS by adding a “Work Activity (WA)” from the CMS homepage, then selecting the “Sec. 704 (a)(4) (FDASIA Sec. 706) Records Request” for the appropriate Center/Office as the “work type.”
When received, the records will be uploaded into the CMS “Sec. 704(a)(4) (FDASIA Sec. 706) Records Request” work activity that was created for the records request.

When the requesting Center or Office sends a confirmation of receipt to the establishment, the communication should be uploaded into the same CMS work activity that was created for the records request.

4. EFFECTIVE DATE

This staff manual guide is effective August 25, 2017.

5. Document History - SMG 9004.1, Policy and Procedures for Requesting Records in Advance of or In Lieu of a Drug Inspection

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