

Guidance for Industry and FDA Staff

**Guidance for Records Access Authority
Provided in Title III, Subtitle A, of the
Public Health Security and Bioterrorism
Preparedness and Response Act of 2002**

FINAL GUIDANCE

This guidance document is being distributed for use by FDA staff and Industry. It is a revision of the previously issued guidance entitled "Draft Guidance for Records Access Authority provided in Title III, Subtitle A of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" dated December 9, 2004.

Comments and suggestions regarding this document may be submitted at any time to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number **2004G-0381**. For questions regarding this document contact Diane Kelley, Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (Tel.) 240-632-6860.

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**U.S. Department of Health and Human Services
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Office of Regulatory Affairs
Office of Enforcement
Division of Compliance Policy**

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this draft guidance.

I. INTRODUCTION

This guidance is intended for the regulated food industry and FDA personnel. The purpose of this guidance document is to clarify the circumstances under which FDA may access and copy records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act"), and describe the procedure that FDA intends to follow to exercise its authority to inspect records under sections 414(a) and 704(a) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act").

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. BACKGROUND

Legal Authority

Section 306 of the Bioterrorism Act (PL 107-188), signed into law on June 12, 2002, created a new section 414, "Maintenance and Inspection of Records," in the FD&C Act. Under this new authority, the Secretary of Health and Human Services (the Secretary) may by regulation establish requirements for persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food to

establish and maintain food records. These records identify the immediate previous sources and the immediate subsequent recipients of food. In addition, section 414(a), "Records Inspection," and section 704(a), "Factory Inspection" authorize the Secretary to access and copy all records related to an article of food if: (1) the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, and (2) the records are necessary to assist the Secretary in making such a determination. FDA plans to carry out its authority to inspect all records and other information described in section 414 in a similar manner as FDA's authority to perform inspections of facilities (i.e., upon presentation of appropriate credentials and a written notice at reasonable times, within reasonable limits, and a reasonable manner.)

On **December 9, 2004**, FDA issued a final rule, entitled "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (69 FR 71561), in which the agency established recordkeeping requirements for persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain food records.

Furthermore, the rule (21 CFR 1.361) specifies the following record availability requirements:

When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the FD&C Act (21 U.S.C. 350c or 374) must be made readily available for inspection and photocopying or other means of reproduction.

III. DISCUSSION

A. Under what circumstances may FDA access and copy records under the Bioterrorism Act?

FDA can use this authority whenever the statutory criteria are satisfied, whether or not intentional adulteration is known or suspected. That is, FDA can access and copy records if: (1) the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, and (2) the records are necessary to assist the Secretary in making such a determination.

FDA employees will not invoke this authority during inspections unless the requirements for record access under the Bioterrorism Act are satisfied.

B. What records may investigators access and copy under the Bioterrorism Act's authority?

Depending upon the circumstances, FDA's authority under sections 414 and 704(a) of the FD&C Act may apply to some or all records that are required to be kept by regulation under section 414(b), as well as any other appropriate records already maintained by the entity. Records associated with an article(s) of food that meet the statutory criteria will be requested. These records may be related to the manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of such food that are maintained by or on behalf of an entity subject to the recordkeeping regulation. The records may be in any format (including paper and electronic formats) and at any location. Because the circumstances of a particular event are case specific, the scope of a record request will vary on a case-by-case basis.

C. What records may FDA not access and copy under the Bioterrorism Act's authority?

FDA's authority under sections 414 and 704(a) of the FD&C Act does not apply to records excluded under section 414(d) (e.g., recipes for food, financial data, pricing data, personnel data, research data, or sales data other than shipment data regarding sales) and records from farms and restaurants. 21 CFR 1.328 defines a "recipe" as "the formula, including ingredients, quantities, and instructions necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe." Accordingly, FDA has authority to access such a list of ingredients in a records request.

D. What procedures does FDA intend to follow before requesting access to records?

Under the authority in Section 306 of the Bioterrorism Act, FDA may access records when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. In those situations when it is necessary to access records under this authority, before any requests for such records access are made by FDA to any affected party, FDA intends to follow these internal procedures:

Notify FDA's Emergency Operations Center (EOC at 301-443-1240 – 24 hours/day) which coordinates the emergency response activities associated with a food article that may present a threat of serious adverse health consequences or death to humans or animals.

1. EOC notifies the appropriate Center (CFSAN and/or CVM) and the Office of Enforcement (OE) in the Office of Regulatory Affairs (either verbally or in writing).
2. The appropriate Center, with the concurrence of OE, determines that there is a reasonable belief an article of food is adulterated and that the food presents a threat of serious adverse health consequences or death to humans or animals.
3. OE concurs with any requests for access to records, and works with the appropriate Center to determine the scope of the request and ensure the requested

records are necessary to assess whether a food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

4. The appropriate Center consults with the Office of the General Counsel, Food and Drug Division (OGC-FD) on the determination of whether there is a reasonable belief an article of food is adulterated. OE will consult with OGC-FD on the scope of the records request.
5. Once all the necessary determinations are made, OE conveys the information to the Director of the district in which the food is located, and, if necessary, coordinates with the District in which the records are maintained.

E. How does FDA intend to make a request to access or copy records under the Bioterrorism Act?

Once FDA follows the procedures in section D above and makes the necessary determination, an investigator or other FDA personnel upon presentation of credentials will submit a written notice, FDA 482c "Notice of Inspection – Request for Records," to the owner, operator, or agent in charge, and inform that person of the records requested and FDA's legal authority to obtain these records. FDA may request additional records related to the implicated food article at a later time under the same authority.

F. How will FDA maintain the confidentiality of any protected information in records it obtains?

Information obtained under the records access provisions of sections 414(a) and 704(a) of the FD&C Act may include, but is not limited to, a company's non-public confidential commercial or trade secret information. Several statutes (e.g., Trade Secrets Act (18 U.S.C. 1905), FD&C Act (21 U.S.C. 331(j)), the Freedom of Information Act, (5 U.S.C. 552) and the agency's information disclosure regulations at 21 CFR 20 and 21 govern the agency's disclosure of information to the public. FDA personnel will comply with all applicable protections, procedures, and legal requirements against the unauthorized disclosure of non-public information, such as any trade secret or confidential commercial information. FDA personnel may disclose non-public information otherwise protected from disclosure to the public, if that disclosure is permitted by law and FDA's procedures. For example, FDA's regulations (set forth in 21 CFR 20 and 21) permit agency officials to disclose certain non-public information to other federal, state, local, or foreign government officials, or to FDA's contractors, when that disclosure is carried out according to law and FDA's procedures.

⁽¹⁾ This guidance has been prepared by the Division of Compliance Policy, Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration.