Contains Nonbinding Recommendations

Release of ORA Laboratory Analytical Results to the Responsible Party: Guidance for Food and Drug Administration Staff

You may submit written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2019-D-1163.

For questions regarding this guidance or additional copies, contact the Office of Regulatory Affairs (ORA) Office of Strategic Planning and Operational Policy (OSPOP) at ORAPolicyStaffs@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Center for Devices and Radiological Health
Center for Food Safety and Applied Nutrition
Center for Tobacco Products
Center for Veterinary Medicine

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Release of ORA Laboratory Analytical Results to the Responsible Party: Guidance for Food and Drug Administration Staff[1]

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I. Introduction

This document provides guidance for FDA staff regarding the release of final and, in some circumstances, preliminary Office of Regulatory Affairs (ORA) laboratory analytical results to the responsible party.[2] This policy applies to samples collected during FDA regulatory activities and analyzed in ORA laboratories. It applies to FDA personnel assigned to deliver and discuss ORA laboratory analytical results with the responsible party. The policy does not require the responsible party to file a Freedom of Information Act (FOIA) request for the records.[3]

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

Sample collection and analysis (which may include finished product and environmental samples) are important tools the FDA uses to assess regulatory compliance of FDA-regulated products and ensure public health protection. In general, the FDA does not release the results of any regulatory testing it conducts until its ORA laboratory analytical results are final and the report is completed, accepted by the responsible FDA official, and any protected information is

[1] This guidance has been prepared by the Office of Strategic Planning and Operational Policy, in the Office of Regulatory Affairs, in cooperation with the Center for Devices and Radiological Health, the Center for Veterinary Medicine, the Center for Tobacco Products, and the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] For purposes of this guidance, the term *responsible party* may include an owner, operator or agent in charge of the site where the regulatory sample is collected, or who may otherwise be responsible for the safety of the product sampled. In some circumstances, more than one responsible party may need to be contacted.

[3] FDA may also share records, including ORA laboratory analytical results, with other entities including state and local governments and other federal agencies in accordance with 21 C.F.R. Part 20, Subpart E.

appropriately redacted.[4] The FDA has processes in place for the release of final ORA laboratory data and analytical results to the responsible party from which the samples are collected.[5,6] However, because certain laboratory tests performed in ORA laboratories may take several weeks to complete, it can be necessary for the Agency to share preliminary results with the responsible party before the final results are confirmed.

This guidance provides a standardized policy on the release of final ORA laboratory analytical results for FDA samples. The FDA will generally release such results when doing so would advance public health goals. This guidance clarifies when and how such results could be released. This document also describes the FDA's policy to orally share, under some circumstances, certain preliminary ORA laboratory analytical results (internally referred to as "Cannot Rule Out" (CRO) results) with the responsible party.[7] A CRO result is a preliminary indication that the sample may yield a final result that could present a public health hazard or threat. A CRO result indicates that the laboratory analytical testing is ongoing, and final results have not yet been determined.

Communicating a CRO result before the FDA confirms the final result is intended to provide the responsible party with information to make informed decisions about potential hazards and products on the market, as well as to consider initiating or preparing to initiate appropriate mitigating strategies to address a potential hazard.

III. Policy

A. Proactive release of CRO ORA laboratory analytical results

1. In general, FDA should not share CRO results until testing is completed.

2. However, FDA may orally release CRO results to the responsible party after clearance in accordance with ORA laboratory procedures if the FDA determines that such release is in the interest of public health. FDA's assessment and consideration of when to release CRO results should include, but not be limited to:

    a. The potential consequences of the injury or illness that could be caused by the regulated product, if it is ultimately confirmed to contain a poisonous or deleterious substance(s) or other hazardous substance, or otherwise deemed to represent a public health threat;
    b. Any background information on the danger associated with the poisonous or deleterious substance(s) or other hazardous substance/situation related to the sample under analysis;

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[4] *See* 21 C.F.R. §§ 20.20(a), 20.105; 21 C.F.R. Part 20, Subpart D.
[5] *See* ORA-LAB,5.10 *Reporting Laboratory Data*, https://www.fda.gov/downloads/ScienceResearch/FieldScience/LaboratoryManual/UCM092171.pdf
[6] For the release of ORA food and food-related environmental laboratory analytical samples, see FMD 147 *Communication of Sample Analysis Results for Food Products and Environmental Samples, https://www.fda.gov/downloads/ICECI/Inspections/FieldManagementDirectives/UCM449001.pdf*
[7] Pursuant to 21 C.F.R.§§ 20.21, 20.105(c), when FDA discloses CRO results to the responsible party, the information is immediately available for public disclosure to any member of the public who requests it.

c. Susceptibility of the consumers that could be affected;
d. The accuracy of the screening method; and
e. Whether release of the CRO results would interfere with an investigation or enforcement proceeding.

3. FDA Centers and Offices that should be consulted before orally communicating CRO results to the responsible party, include but are not limited to:

    a. For-cause inspections:
        i. For CRO results for samples collected as part of a for-cause inspection (e.g., follow-up to a recall, patient death/injury, or consumer complaint), ORA should collaborate with the respective Center to coordinate strategy prior to communicating with the responsible party.

    b. Outbreaks and emergencies:
        i. For CRO results that are associated with a human or animal food or cosmetic outbreak being coordinated by the FDA Coordinated Outbreak Response and Evaluation Network (CORE), ORA should collaborate with CORE, the respective Center, and Centers for Disease Control and Prevention (CDC), to coordinate strategy prior to communicating with the responsible party.[8]
        ii. For CRO results associated with other FDA-regulated products related to a public health emergency, ORA should collaborate with the FDA's Office of Emergency Operations and the respective Center to coordinate strategy prior to communicating with the responsible party.

    c. Concerns about the sterility of products labeled "sterile:"
        i. For CRO results associated with sterile injectable, inhalation, topical or ophthalmic drug products, ORA should collaborate with the respective Center or, if necessary, the Counter-Terrorism and Emergency Coordination Staff to coordinate strategy prior to communicating with the responsible party.
        ii. For CRO results associated with sterile medical devices, ORA should coordinate with the respective Center to coordinate strategy prior to communicating with the responsible party.

    d. Other situations associated with a public health risk:
        i. When deemed appropriate by the ORA program director, and in accordance with a strategy developed in collaboration with the respective Center, CRO results may be communicated to the responsible party.

[8] State partners should also be included in communications with the responsible party, in accordance with ORA's Field Bulletin 61: Inviting State Partners on Calls with Firms to Explain CDC Epidemiological or Laboratory Data During Outbreak Investigations.

4. Any release of CRO results should include the disclaimer statement below. When results are communicated orally to the responsible party, the FDA official releasing the CRO results should read the statement to the responsible party and document doing so.

> *Disclaimer: "Cannot rule out" sample results are preliminary in nature. They are being shared at this time for informational purposes only. Although this information should be considered as one component of a larger evaluation of product safety, the FDA's communication of these preliminary results does not imply that any future action by any government agency or private party is necessary or appropriate. Final Office of Regulatory Affairs (ORA) laboratory analytical results will be provided as soon as practicable after they become available. However, you remain responsible for assuring the quality and safety of all products you have released to the market. The FDA is not responsible for the consequences of any private party's decision to act, or to not act, on the "cannot rule out" results. More information about "cannot rule out" ORA laboratory results is available at [Provide link to this guidance].*

B. Release of final ORA laboratory analytical results

Upon request by the responsible party (either received by FDA orally or in writing), the FDA may, at its discretion or if mandated by law,[9] release final ORA laboratory analytical results for samples that were collected during FDA regulatory activities. The final results may be provided to the responsible party without the need to file a request that is formally designated as a FOIA request. Releasing final ORA laboratory analytical results in this manner allows the responsible party to take appropriate action, and/or resume normal operation based on the results.

1. In situations where a responsible party is voluntarily holding product, or holding product under the conditions set forth in the import entry bond, pending final ORA laboratory analytical results, the FDA may orally notify the responsible party of the final laboratory analytical results. Written notification may follow at FDA's discretion or if required by law. FDA personnel should document the details of the notification discussion, as well as the responsible party's response.

2. In limited cases, FDA may withhold the release of ORA laboratory analytical results, e.g. if the release is reasonably expected to interfere with an investigation or enforcement proceeding.

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[9] *See, e.g.*, section 704(d) of the Federal Food, Drug and Cosmetic Act, which requires that, "[w]henever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, *a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge*." (emphasis added).