

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>ORA Laboratory Manual Volume II</i></p>	<p style="text-align: center;"><b>Document Number:</b>  ORA-LAB.5.10</p>	<p style="text-align: center;"><b>Revision #: 02</b>  <b>Revision Date:</b>  06/06/2019</p>
<p>Title: <span style="float: right;"><b>Reporting Laboratory Results</b></span></p>		<p style="text-align: center;">Page 1 of 12</p>

## Sections in This Document

1. Purpose .....	2
2. Scope .....	2
3. Responsibility.....	2
4. Background.....	3
5. References .....	3
6. Procedure .....	3
6.1. Introduction .....	3
6.2. Results .....	4
6.2.1. Analytical Worksheet .....	4
6.2.2. Collection Report .....	5
6.2.3. General Continuation Sheets.....	5
6.2.4. Attachments .....	5
6.3. Field Accomplishments and Compliance Tracking System (FACTS) or a Laboratory Information System (LIMS) .....	5
6.4. Other .....	6
6.5. Deviations and modifications .....	6
6.6. Additional analysis .....	6
6.7. Opinions and Interpretations .....	7
6.8. Reviewing Analytical Results .....	7
6.9. Authorizing Analytical Results Prior to Release .....	7
6.10. Reporting.....	7
6.10.1. Reports issued to internal (within FDA) offices .....	7
6.10.2. Abbreviated reporting.....	7
6.10.3. Reports issued to agents responsible for any products tested by an ORS laboratory 8	
6.10.4. Reports issued in cooperation with industry and other Federal and State agencies 8	
6.11. Format of Reports .....	9
6.12. Issuing Modifications or Amendments to Reported Findings .....	10
7. Glossary/Definitions.....	10
8. Records .....	11
9. Supporting Documents .....	11

<b>FOOD AND DRUG ADMINISTRATION</b> <b>OFFICE OF REGULATORY AFFAIRS</b> <i>ORA Laboratory Manual Volume II</i>	<b>Document Number:</b> ORA-LAB.5.10	<b>Revision #: 02</b> <b>Revision Date:</b> 06/06/2019
Title: <p style="text-align: center;"><b>Reporting Laboratory Results</b></p>		Page 2 of 12

10. Document History .....	12
11. Change History .....	12
12. Attachments.....	12

---

### 1. Purpose

This procedure defines the process for reporting analytical findings and conclusions as prescribed by the agency.

---

### 2. Scope

This procedure applies to all Office of Regulatory Science (ORS) laboratories and the release of information.

---

### 3. Responsibility

#### A. Laboratory Director:

1. is responsible for ensuring the timeliness, accuracy and completeness of all analytical information reported by the laboratory; and
2. reviews, or designates reviews of violative worksheets prior to release by the laboratory.

#### B. Laboratory Management:

1. are responsible for ensuring the timeliness, accuracy and completeness of all analytical information reported by the analyst;
2. are responsible for ensuring that laboratory analysts comply with the data and information recording procedures; and
3. review analytical findings and supporting records generated by analysts, enter related conclusions, and sample classification codes into web application, such as Field Accomplishments and Compliance Tracking System (FACTS) or Laboratory Information Management System (LIMS).

#### C. Analysts:

1. are responsible for capturing and recording accurate and complete analytical information on worksheets, continuation sheets, electronic
-

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>ORA Laboratory Manual Volume II</i></p>	<p style="text-align: center;"><b>Document Number:</b>  ORA-LAB.5.10</p>	<p style="text-align: center;"><b>Revision #: 02</b>  <b>Revision Date:</b>  06/06/2019</p>
<p>Title:</p> <p style="text-align: center;"><b>Reporting Laboratory Results</b></p>		<p style="text-align: center;">Page 3 of 12</p>

lab notebooks, or other records in accordance with the instructions of this procedure; and

2. are to complete worksheets and enter analytical observations and findings into the web application, such as FACTS or LIMS, in a timely manner.

#### 4. Background

None

#### 5. References

- A. Food, Drug and Cosmetic Act, Section 704(d), Factory Inspection
- B. Field management directive No. 147, procedure for release of analytical results pursuant to section 704(d).
- C. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories. Section 7.8.
- D. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals – An Aid to Interpretation of ISO/IEC 17025:2017; August 2018.

#### 6. Procedure

##### 6.1. Introduction

The worksheets printed or electronic, and applicable supporting records (e.g., labels, packaging, promotional materials, instrument charts, exhibits, memorandums, controls) referred to in this section are used to provide the written or electronic account of analytical findings that either support regulatory action or serve to classify the sample as non-actionable. This documentation is prepared so the history of the sample can be reconstructed with confidence, including details on which the analyst may respond to queries or challenges months or years later. They give an objective account of the sample handling and analysis efforts from the time of receipt to the time analysis and investigative efforts are concluded. There is no doubt about what was done, how it was done, who did it, and with what accuracy and precision the work was accomplished.

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <b>ORA Laboratory Manual Volume II</b></p>	<p style="text-align: center;"><b>Document Number:</b>  ORA-LAB.5.10</p>	<p style="text-align: center;"><b>Revision #: 02</b>  <b>Revision Date:</b>  06/06/2019</p>
<p>Title:</p> <p style="text-align: center;"><b>Reporting Laboratory Results</b></p>		<p style="text-align: center;">Page 4 of 12</p>

The worksheet package or electronic file presents a complete picture that can be understood by reviewers, even those not technically or scientifically trained, and not a part of the analyzing science unit.

## 6.2. Results

Analytical findings are presented on the basic worksheets, FDA form FD-431 (Analyst Worksheet) and FD-431a (General Continuation Sheet) or electronic templates, in a clear and concise manner to expedite interpretation of the results, especially by non-technical and non-scientific personnel. These forms and attachments or electronic lab notebooks make an analytical package or electronic file. Whenever possible, the analytical data should be tabulated.

Also, if subsamples with differing codes were individually examined, the results are clearly recorded for each code because regulatory action may be based on the results of a particular code exclusive of other codes. The following are some components of the analytical package.

### 6.2.1. Analytical Worksheet

The following information is included on the analytical worksheet:

- A. Title (i.e. ANALYST WORKSHEET), Block 10 Summary of Analysis;
- B. Name of laboratory (e.g. DENL);
- C. Unique identification of the worksheet on each page (i.e. sample number and page numbering);
- D. Identification of the method used;
- E. Description of sample to include deviations, additions or exclusions from collector's report;
- F. Date received;
- G. Date(s) analysis performed;
- H. Date reported;
- I. Results;

*NOTE: Results include the unit of measurement and reflect the correct number of significant figures indicated by the analytical method. If computer generated results are included in the final report, a statement on the report indicating the correct number of significant figures suffices when the number of figures presented by the computer exceeds the capability of the method. Statistical or other data reflecting accuracy and precision are included.*

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <b>ORA Laboratory Manual Volume II</b></p>	<p style="text-align: center;"><b>Document Number:</b>  ORA-LAB.5.10</p>	<p style="text-align: center;"><b>Revision #: 02</b>  <b>Revision Date:</b>  06/06/2019</p>
<p>Title: <b>Reporting Laboratory Results</b></p>		<p style="text-align: center;">Page 5 of 12</p>

*Analytical results are compared with the label, labeling declarations, published tolerances and standards, regulatory action levels, manufacturer's specifications or other applicable criteria.*

*When requested, a statement of compliance or non-compliance with requirements or specifications is recorded.*

*When discrepancies are found between analytical results and labeling statements or other criteria, these facts are set out clearly.*

J. Analyst and reviewer signatures.

### **6.2.2. Collection Report**

The report includes, but is not limited to the following information:

- A. Name of sampling district;
- B. Date of sampling;
- C. Identification of the substance, material or product sampled;
- D. Reason for collection;
- E. Method of collection, how prepared; and
- F. Analysis requested.

### **6.2.3. General Continuation Sheets**

These sheets contain the raw data, calculations, standard preparation, dilution schemes, quality control data, equipment used, reagents, media, test conditions, deviations, additions or exclusions from the test method, and other sample related information.

### **6.2.4. Attachments**

Attachments can consist of:

- A. Instrument generated reports and charts
- B. Photographs,
- C. Labels
- D. Memoranda

## **6.3. Field Accomplishments and Compliance Tracking System (FACTS) or a Laboratory Information System (LIMS)**

Analytical findings and observations are entered into FACTS or LIMS by laboratory analysts. Supervisors enter conclusions and laboratory classification. The individuals performing the laboratory activities are recorded

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>ORA Laboratory Manual Volume II</i></p>	<p style="text-align: center;"><b>Document Number:</b>  ORA-LAB.5.10</p>	<p style="text-align: center;"><b>Revision #: 02</b>  <b>Revision Date:</b>  06/06/2019</p>
<p>Title:</p> <p style="text-align: center;"><b>Reporting Laboratory Results</b></p>		<p style="text-align: center;">Page 6 of 12</p>

in FACTS. The data is obtained by internal clients (FDA) through FACTS or electronic file transmission. Laboratory personnel are to make every effort possible to ensure the sample information, analytical findings and conclusions entered are correct and that any errors are corrected as quickly as possible.

#### **6.4. Other**

The following information is found at the laboratory, but not necessarily provided in the analytical packet or web application:

- A. Address of the analyzing laboratory;
- B. Address and contact information of the sampling district;
- C. Statement to the effect that the results relate only to the item tested;  
and
- D. Estimated uncertainty of measurement

#### **6.5. Deviations and modifications**

Whenever there is a need to (a) deviate from or add to an official method, (b) use an entirely new method for a sample analysis or (c) modify test conditions such that it may affect the integrity of the analysis and interpretation of results, these deviations or new methods are comprehensively described by the analyst. Depending upon the magnitude of the deviation or change, this can be a relatively short entry on a continuation sheet (FD-431a), web application comment section, or as a separate memo. This memorandum describes the deviations and new methods employed and how the proper performance of the new or modified method was demonstrated in terms of accuracy, precision, specificity for the product being analyzed, and the estimated uncertainty of the measurements when this is needed for the validity or application of the examination. The validation techniques used will vary depending upon the situation.

#### **6.6. Additional analysis**

Whenever a check or additional analysis is performed, a new FD-431 or electronic lab notebook is started. However, blocks 8 and 9 need not be repeated on these second worksheets. In addition, the description of the container, labeling, code in block 10 on the second worksheet need not be repeated unless requested or instructed to do so. For those items remaining the same on the second worksheet, enter the statement See original analysis, and under the analysis category enter the subsample numbers retested whenever applicable. The information entered in block 7 is complete in description to demonstrate continuity of sample handling.

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>ORA Laboratory Manual Volume II</i></p>	<p style="text-align: center;"><b>Document Number:</b>  ORA-LAB.5.10</p>	<p style="text-align: center;"><b>Revision #: 02</b>  <b>Revision Date:</b>  06/06/2019</p>
<p>Title:</p> <p style="text-align: center;"><b>Reporting Laboratory Results</b></p>		<p style="text-align: center;">Page 7 of 12</p>

### 6.7. Opinions and Interpretations

The laboratory management interprets the analytical findings and assigns a sample classification in FACTS or LIMS. The laboratory classifications are defined in the ORA Laboratory Manual Volume III Section 3. Other opinions and interpretations by laboratory management may be included in the analytical package. These may be comprised of, but not limited to the following records:

- A. Opinion on the conformity of the results with regulatory requirements;
- B. Recommendations on how to use the results; and
- C. Guidance to be used for improvements, when needed and applicable.

### 6.8. Reviewing Analytical Results

- A. Worksheet Check –A second qualified analyst or supervisor will review the package prior to it being forwarded to final reviewing official.
- B. Supervisor Review – Following the worksheet check, a supervisor reviews it for accuracy and completeness.

### 6.9. Authorizing Analytical Results Prior to Release

Analytical packages for non-actionable samples will be approved by the responsible Supervisor or designee. Analytical packages for actionable samples are approved by the laboratory director or designee. The responsible Supervisor or Laboratory Director enters their conclusion(s) and sample classification code(s) into FACTS.

### 6.10. Reporting

#### 6.10.1. Reports issued to internal (within FDA) offices

Reporting laboratory findings to compliance and other internal FDA offices is accomplished using the FACTS application, LIMS, or, if applicable, via distribution of an analytical package to the division responsible for the sample. Each laboratory maintains a record of package distributions.

#### 6.10.2. Abbreviated reporting

Analytical findings and conclusions may also be reported using abbreviated procedures designed to minimize laboratory resources when such is authorized by the laboratory director, the Office of Regulatory Science (ORS) Headquarter Units, and the applicable compliance program. The exact manner in which abbreviated reporting is accomplished is determined on a case by case basis to meet client needs.

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>ORA Laboratory Manual Volume II</i></p>	<p style="text-align: center;"><b>Document Number:</b>  ORA-LAB.5.10</p>	<p style="text-align: center;"><b>Revision #: 02</b>  <b>Revision Date:</b>  06/06/2019</p>
<p>Title:</p> <p style="text-align: center;"><b>Reporting Laboratory Results</b></p>		<p style="text-align: center;">Page 8 of 12</p>

**6.10.3. Reports issued to agents responsible for any products tested by an ORS laboratory**

- A. Section 704(d) of the Food, Drug and Cosmetic Act requires that the results of an analysis of a sample obtained during an inspection of an establishment where food is manufactured, processed or packaged be reported promptly to the owner, operator, packer or agent in charge.
- B. Form FDA 1551 shall be mailed or faxed to the responsible firm within two (2) working days of approval of the Sample Summary Report. The sample description includes the following:
  - 1. The nature of the sample, number and size of the units examined, and the code marks of the subdivisions examined.
  - 2. The results of analysis described in simple (lay) terms whenever possible, and restricted to addressing filth, decomposition or other factors causing the food to be unfit for food. Details should be given regarding any factors in the analysis that are significant in terms of the possible violation. A general summary should be provided on factors that are not significant.
  - 3. Form FDA 1551 shall not list the methods employed, conclusions drawn from the analysis, any details regarding the manner in which the sample was handled prior to the analysis, explanation of the type of examination made, or the results of examinations for factors other than filth, decomposition, or those causing the food to be unfit for food. These forms shall also not be mailed to other than the owner or manufacturer, processor or packer from whom the sample was collected.

**6.10.4. Reports issued in cooperation with industry and other Federal and State agencies**

- A. Unsolicited requests for analytical results on any product may be sent to any firm, individual or cooperating agency that, in the judgment of the responsible program, has a legitimate interest in the results and when a useful purpose will be served.
- B. Specific guidance regarding when and how laboratory information is to be shared will be provided by the division responsible for the products involved on a case-by-case basis.
- C. On occasions where a laboratory enters into an interagency agreement with an external agency (i.e. State or local agency) to share analytical test results on the food, drug, cosmetic or medical device products being tested, this data is shared in compliance with the established



<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>ORA Laboratory Manual Volume II</i></p>	<p style="text-align: center;"><b>Document Number:</b>  ORA-LAB.5.10</p>	<p style="text-align: center;"><b>Revision #: 02</b>  <b>Revision Date:</b>  06/06/2019</p>
<p>Title:</p> <p style="text-align: center;"><b>Reporting Laboratory Results</b></p>		<p style="text-align: center;">Page 9 of 12</p>

agreement. As a minimum, this agreement includes terms and limitations designed to protect the privacy of the clients whose products have been tested.

### **6.11. Format of Reports**

The general format of the analyst worksheet consists of three parts:

A. Heading which includes these items:

1. Product,
2. Sample number,
3. Seals,
4. Date received,
5. Received from,
6. Lab,
7. Description of sample,
8. Net Contents, and
9. Labeling.

B. Body or Summary of Analysis which includes these subparts:

1. Container,
2. Labeling,
3. Code,
4. Product,
5. Analysis,
6. Method, and
7. Results.

C. Closing which includes vital information:

1. Reserve sample,
2. Conclusion
3. Signatures (worksheet check) on hard-copy worksheet,
4. Date reviewed on hard-copy worksheet, and
5. Date reported on hard-copy worksheet.

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>ORA Laboratory Manual Volume II</i></p>	<p style="text-align: center;"><b>Document Number:</b>  ORA-LAB.5.10</p>	<p style="text-align: center;"><b>Revision #: 02</b>  <b>Revision Date:</b>  06/06/2019</p>
<p>Title:</p> <p style="text-align: center;"><b>Reporting Laboratory Results</b></p>		<p style="text-align: center;">Page 10 of 12</p>

## 6.12. Issuing Modifications or Amendments to Reported Findings

Material amendments to analytical results that have already been reported are made only in the form of an additional record or data transfer. These reports are flagged at top left corner on FDA 431 as Additional Analysis or Amended Report with the sample identification (unique package or sample number). These amendments are to clearly identify the sample or samples involved and describe the changes, additions and corrections being made and the rationale for why they are needed. The requesting official must also be contacted with notification of the amended report.

Transcription errors that do not affect the data, i.e. incorrect dates, are changed on the original analyst worksheet or if applicable, in FACTS or LIMS.

## 7. Glossary/Definitions

- A. Original analysis – The initial examination conducted on a representative portion of the sample is an original analysis.
- B. Check analysis – An analysis performed by a second qualified analyst to confirm a finding that may be used by FDA or cooperating agencies in a regulatory action is a check analysis.
- C. Additional analysis – Additional analyses performed on a sample to obtain information not provided by the original set of analyses or to verify originally reported analytical results is an additional analysis. Additional analysis may be performed on the original sample composite or extract, or an intact and unanalyzed unit of the sample.
- D. Amended report – corrected report due to error or change that directly affects data
- E. Compliance sample – A compliance sample is collected on a selective basis as the result of an inspection, complaint or other evidence that there may be a problem with the commodity.
- F. Surveillance sample – A surveillance sample is collected on an objective basis where there is no evidence or suspicion of a problem with the commodity.
- G. Consumer Complaint Sample – A consumer complaint sample is collected from a consumer who is registering an official complaint (verbal or written) regarding the quality of a FDA regulated product.
- H. Follow-up (sample) to consumer complaint –A follow-up sample is often denoted by FU to CC. A follow-up to a consumer complaint is a sample

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>ORA Laboratory Manual Volume II</i></p>	<p style="text-align: center;"><b>Document Number:</b>  ORA-LAB.5.10</p>	<p style="text-align: center;"><b>Revision #: 02</b>  <b>Revision Date:</b>  06/06/2019</p>
<p>Title:</p> <p style="text-align: center;"><b>Reporting Laboratory Results</b></p>		<p style="text-align: center;">Page 11 of 12</p>

collected as a result of a complaint but not collected from the complainant.

- I. Dealer holding sample – A dealer holding sample indicates that the dealer is holding the lot sampled. Normally, the dealer would like to be notified of the analytical results as soon as possible.
- J. Split sample – A split sample indicates one portion of the sample is in the possession of one science unit and another portion has been sent to another science unit.
- K. Sample classifications – Samples are assigned to different regulatory decision-making classes (1-5) by laboratory supervisors based upon the results of the laboratory’s examination.
- L. Factory food samples – Factory food samples consist of raw materials, in-process, and finished products collected to demonstrate manufacturing conditions and are flagged as such on the FACTS collection report.

## 8. Records

- A. FACTS data
- B. LIMS data
- C. Analytical package
- D. Abbreviated packages
- E. Form FDA 1551
- F. Reports to industry
- G. Modifications and amendments to reported findings
- H. Import Salmonella Template
- I. Drug Survey Template

## 9. Supporting Documents

- A. Regulatory Procedures Manual (RPM)
- B. FACTS Reference Guides
- C. LIMS Reference Guides

<b>FOOD AND DRUG ADMINISTRATION</b> <b>OFFICE OF REGULATORY AFFAIRS</b> <i>ORA Laboratory Manual Volume II</i>	<b>Document Number:</b> ORA-LAB.5.10	<b>Revision #: 02</b> <b>Revision Date:</b> 06/06/2019
Title: <p style="text-align: center;"><b>Reporting Laboratory Results</b></p>		Page 12 of 12

## 10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.2	R	11/16/05	LMEB	LMEB
1.3	R	08/15/08	LMEB	LMEB
1.4	R	01/22/13	LMEB	LMEB
1.5	R	05/08/14	LMEB	LMEB
02	R	06/06/2019	LMEB	LMEB

\* - D: Draft, I: Initial, R: Revision

## 11. Change History

Revision #	Change
02	Revisions made as needed to align this procedure with new ISO/IEC 17025 and AOAC requirements. Revision to formatting and policy clarifications were also made.

## 12. Attachments

None