Collecting and Providing 702(b) Portions of FDA Official Samples

Questions and Answers

Guidance for Industry and FDA Staff

DRAFT GUIDANCE

This draft guidance document is for comment purposes only.

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For questions regarding this draft document 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 Biologics Evaluation and Research
Center for Drug Evaluation and Research
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine

January 2022

Contains Nonbinding Recommendations

Draft – Not for Implementation

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Contents

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

INTRODUCTION

This draft guidance is intended to assist FDA staff and industry with issues and questions related to the requirements for FDA to collect and provide portions of official samples under section 702(b) of the Federal Food, Drug, & Cosmetic Act (FD&C Act) and its implementing regulation in Title 21 Code of Federal Regulations (CFR) section 2.10 (21 CFR 2.10).

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, 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.

BACKGROUND

Section 702 of the FD&C Act (21 U.S.C. 372) authorizes FDA to conduct examinations and investigations and to collect samples.[1] Collecting samples is a critical part of FDA's regulatory activities. Under section 702(b) of the FD&C Act (21 U.S.C. 372(b)), when FDA collects a sample of a food, drug, or cosmetic for analysis, FDA must, "upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent" (hereinafter referred to as "owner"). Section 702(b) of the FD&C Act also authorizes FDA to establish, by regulation, "reasonable exceptions

[1] Courts have recognized that the plain language of section 702(b) of the FD&C Act authorizes sampling. *See*, *e.g., United States v. 75 cases, etc.*, 146 F.2d 124 (4th Cir. 1944).

from, and impose such reasonable terms and conditions relating to" the requirements of section 702(b) of the FD&C Act, as necessary for the proper administration of the provisions of the FD&C Act.

FDA's regulation at 21 CFR 2.10 was established to describe those reasonable terms and conditions to implement section 702(b) of the FD&C Act. The regulation provides a definition for official sample, states when FDA must collect and provide a part of the official sample (hereinafter referred to as the 702(b) portion) to the owner, and states when FDA may destroy the official sample, among other things. The regulation also provides exceptions to the requirement for FDA to collect and provide a 702(b) portion of an official sample to the owner.

A. TERMINOLOGY

1. What is a 702(b) portion?

FDA uses the term 702(b) portion to refer to the part of FDA's official sample of a food, drug, or cosmetic that FDA is required to provide to the owner, upon request under section 702(b) of the FD&C Act. FDA will collect and provide a 702(b) portion in accordance with 702(b) of the FD&C Act and its implementing regulation in 21 CFR 2.10.

2. What is an official sample?

A sample collected by an officer or employee of the U.S. Department of Health and Human Services (HHS) is an official sample if records or other evidence is obtained by the officer or employee or any other officer or employee of HHS indicating that the shipment or other lot of the article from which the sample is collected was introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory as defined in section 201(a)(2) of the FD&C Act. 21 CFR 2.10(a)(1). The officer or employee of HHS must designate such sample as an official sample for it to be considered one. 21 CFR 2.10(a)(1). FDA personnel can refer to FDA's Investigations Operations Manual (IOM), Chapter 4, for instructions related to official samples.

3. What is a food, drug, or cosmetic?

The FD&C Act defines food, drug, and cosmetic in pertinent part as:

- Food means "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article" (section 201(f)); For example,

  - A dietary supplement is deemed to be food (section 201(ff))[2]
  - A food additive is a component of food (section 201(s)).
- Drug means "(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)" (section 201(g)(1)).[3]
- Cosmetic means "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap" (section 201(i)).

FDA occasionally performs environmental sampling (e.g. swabbing of facilities or equipment) to identify the presence of chemicals or microbes where food, drugs, or cosmetics are produced. These environmental samples do not meet the definitions of food, drug, or cosmetic.

B. QUESTIONS AND ANSWERS

1. When must FDA collect a 702(b) portion?

FDA must collect a 702(b) portion when an officer or employee of HHS collects an official sample of a food, drug, or cosmetic for analysis under the FD&C Act, unless an exception in 21 CFR 2.10(b) applies (See B.3.).

i. Must a commissioned state or local official collect a 702(b) portion when collecting an official sample?

[2] Section 201(ff)(3)(B) of the FD&C Act (21 U.S.C. 321(ff)(3)(B)) excludes from the definition of a dietary supplement a product that contains an article that was the subject of an investigational new drug exemption, new drug application, or biologics license application 1) approved as a new drug under section 505 of the FD&C Act, certified as an antibiotic under 507 of the FD&C Act, or licensed as a biologic under section 351 of the Public Health Service Act, or 2) investigated as a new drug, antibiotic or biologic for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public; and which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under the FD&C Actprior to its marketing as a dietary supplement.

[3] A biological product, as defined in section 351(i)(1) of the Public Health Service Act (PHS Act), that is also regulated as a drug under the FD&C Act's drug provisions is subject to section 702(b) (see section 351(j) of the PHS Act), as is a combination product that is subject to premarket approval under the FD&C Act's drug provisions or the PHS Act's biologics licensing provisions.

Section 702(a)(1)(A) of the FD&C Act authorizes the Secretary of HHS to conduct examinations and inspections through officers and employees of HHS or through certain officers and employees of states, territories, and political subdivisions who have been duly commissioned as an officer of HHS. Under section 702(a)(1)(A) of the FD&C Act, state and local officials duly commissioned by FDA are considered officers of HHS when conducting examinations or investigations under contract or agreement for purposes of the FD&C Act. Thus, a commissioned state or local officer or employee who collects an official sample of a food, drug, or cosmetic for analysis under the FD&C Act must collect a 702(b) portion, as required by 21 CFR 2.10(b). This guidance uses the terms "FDA staff" and "FDA investigator" to refer to an HHS officer or employee, including a commissioned state or local officer or employee.

ii. Should FDA collect a 702(b) portion if documentation of interstate commerce is not immediately available?

An FDA investigator must collect a 702(b) portion for an official sample, unless an exception applies. (See 21 CFR 2.10(a)(1) and section A.2. of this guidance for the meaning of official sample, which includes, among other things, evidence of interstate commerce.)

In some situations, such as a retail setting or as part of FDA's surveillance activities, records or evidence of interstate commerce may not be immediately available at the time of the sample collection. However, if FDA has reason to believe that the product was introduced into or in interstate commerce and expects to obtain evidence of interstate commerce at a later time, FDA should collect a 702(b) portion for the sample.

iii. What common types of samples does FDA collect that do not require a 702(b) portion?

FDA is not required to collect or provide a 702(b) portion for samples of products that are not foods, drugs, or cosmetics as defined by the FD&C Act. (21 U.S.C. 372(b); 21 CFR 2.10(b)). See section A.3 of this guidance for the definitions of food, drug, and cosmetic. For example, FDA is not required to collect a 702(b) portion for a sample that is a medical device or a tobacco product.

Other examples of samples collected by FDA that are not a food, drug, or cosmetic and thus are not subject to section 702(b) of the FD&C Act include filth exhibits that are not tied to or connected to a specific lot of product used to illustrate conditions at an establishment (e.g., rodent excreta pellets) and samples collected from equipment or surfaces to demonstrate the environmental conditions of an establishment. However, unless an exception in 21 CFR 2.10(b) applies, FDA must collect a 702(b) portion when collecting an official sample of a food, drug, or cosmetic that is associated with the filth or the environmental sample.

2. What are the exceptions to 702(b) portion collection?

An FDA investigator who is collecting an official sample of a food, drug, or cosmetic for analysis under the FD&C Act must collect at least twice the quantity estimated to be sufficient for analysis, unless one of the following exceptions in 21 CFR 2.10(b) applies:

> (1) The amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated, in which case the FDA investigator must collect as much as is available and reasonably accessible.
>
> *Considerations:* For some samples, such as when FDA is collecting an official sample from retail, rather than from the owner, the amount of the article available and reasonably accessible for sampling is less than twice the quantity estimated to be sufficient for analysis. Also, FDA may receive product from a consumer that the consumer alleges violates the FD&C Act in some respect. The consumer may have a limited portion of the article that is not sufficient to include a 702(b) portion. In these and other situations for which twice the quantity sufficient for analysis is not available, FDA should collect as much of the article that is available and reasonably accessible.
>
> (2) The cost of twice the quantity so estimated exceeds $150.
>
> *Considerations*: If the cost of twice the quantity exceeds $150, FDA investigators should consult with their supervisors (see IOM, Chapter 4).
>
> (3) The sample cannot by diligent use of practicable preservation techniques available to FDA be kept in a state in which it could be readily and meaningfully analyzed in the same manner and for the same purposes as FDA's analysis.
>
> *Considerations*: Whether the sample can be so preserved and analyzed may depend on the product from which the sample was taken. For example, some FDA products, such as fresh produce, are highly perishable and cannot be kept in a state that allows for meaningful analysis in the same manner and for the same purpose as the FDA's analysis.
>
> (4) The sample is collected from a shipment or other lot which is being imported or offered for import into the United States.
>
> (5) The sample is collected from a person named on the label of the article or his agent, and such person is also the owner of the article.
>
> (6) The sample is collected from the owner of the article, or his agent, and such article bears no label or, if it bears a label, no person is named thereon.

For exceptions (5) and (6), while FDA is not required to collect a 702(b) portion, the owners or their agents may decide at their own discretion to collect a sample to duplicate FDA's sample. Such sampling by owners or their agents is outside the scope of this guidance.

FDA may collect a 702(b) portion even if an exception applies. For example, if an official sample of an imported article, or article offered for import, is collected for use in an anticipated legal action (e.g., seizure under section 304 of the FD&C Act), FDA may collect a 702(b) portion.

3. When FDA receives a food, drug, or cosmetic as part of a consumer complaint, should FDA collect a 702(b) portion?

Yes, when collecting an official sample from a consumer as part of a consumer complaint, FDA should take reasonable efforts to collect a 702(b) portion if one is available and no exceptions apply.

4. Does FDA collect the 702(b) portion as a separate subsample?

FDA is not required to collect the 702(b) portion as a separate subsample. In some situations, when collecting, FDA may not be able to collect a separate subsample that will be used as the 702(b) portion of the official sample.

However, whenever possible, FDA may collect a separate subsample in order to provide the owner a 702(b) portion. See IOM Chapter 4. If FDA does not collect separate subsamples, FDA will collect a single sample at least twice the amount estimated to be sufficient for analysis unless an exception applies. (21 CFR 2.10(b)).

5. When must FDA provide a 702(b) portion?

21 CFR 2.10(c) establishes when FDA must provide a 702(b) portion to the owner of the sampled product. Under 2.10(c), after FDA has completed all analysis of an official sample of a food, drug, or cosmetic needed to determine whether the product is adulterated or misbranded, or otherwise subject to the prohibitions of the FD&C Act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise based on the sample, a part of the sample, if any remains available, must be provided for analysis upon written request, by the owner, unless an exception applies.

i. If the only portion of the official sample that remains after FDA analysis is the amount reserved by FDA for use at trial, must FDA provide that portion to the owner?

No, FDA is not required to give a 702(b) portion to the owner if none remains after reserving an adequate amount for trial. Under such situations, FDA is not required to provide to the owner the portion reserved by FDA for use at trial. (21 CFR 2.10(c)).

ii. If a portion of an official sample remains after FDA analysis and reserving an amount for use at trial, must FDA provide part of the sample upon written request by the owner?

Yes, FDA must provide a portion of the official sample to the owner if any remains after reserving an amount for trial upon written request by the owner. (21 CFR 2.10(c)).

iii. If the sample was collected from a consumer as part of a consumer complaint, must FDA provide a part of the sample to the consumer?

In some consumer complaint situations, there is potential for litigation between the consumer and the firm, in addition to any action FDA may be considering. In such situations, both the firm and the consumer may request a part of the sample.

FDA is required to provide a 702(b) portion if, in part, the request is from any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner. (21 U.S.C. 372(b)). 21 CFR 2.10(a)(3) states that the "owner of a food, drug, or cosmetic of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected." FDA may consider providing a portion of a sample to a consumer who is not an owner but such portion is outside the scope of this guidance, and FDA must prioritize providing a sample to persons entitled to a 702(b) portion under the FD&C Act.

6. If FDA is required to provide a 702(b) portion, how much should FDA provide?

21 CFR 2.10(c) states, in part, that FDA must provide "a part of the sample" to the owner upon written requests, unless an exception applies. The amount of a sample that remains for providing a 702(b) portion depends on the amount of sample collected, the amount of the sample used for the analysis, and the amount of the sample reserved for trial. The amount reserved for trial is what FDA estimates to be adequate for use as exhibits in the trial of any case that may arise under the FD&C Act based on the sample and will be determined at FDA's discretion.

If it is not possible to provide the amount requested by the owner, FDA should consult with the owner to determine how much of the remaining sample the owner may want as a 702(b) portion.

7. If FDA collected one or more separate subsamples as the 702(b) portion, but the owner requests a portion of the subsample FDA used for the sample analysis, should FDA provide the portion the owner requested?

Although not required, FDA's practice is to, whenever reasonable, collect separate subsamples to serve as the 702(b) portion. Also see section B.5.

If FDA collected a separate subsample as the 702(b) portion but the owner requests a portion from the subsample FDA used for analysis, FDA may provide the owner the portion from the source requested, if any remains available after analysis and reserving an amount adequate for

use at trial. FDA Divisions receiving such requests may consult within FDA about the circumstances pertaining to the request.

8. How long should a 702(b) portion be retained?

FDA should retain the 702(b) portion until it is authorized to destroy it. Under 21 CFR 2.10(e), FDA is authorized to destroy an official sample, including the 702(b) portion, as follows:

a. FDA determines that no analysis of the sample will be made;
b. FDA determines that no notice under section 305 of the FD&C Act and no case under the FD&C Act, is or will be based on the sample;
c. The sample was the basis of a notice under section 305 of the FD&C Act and, after opportunity for presentation of views following such notice, FDA determines that no other such notice, and no case under the FD&C Act, is or will be based on the sample;
d. The sample was the basis of a case under the FD&C Act that has gone to final judgment, and FDA has determined that no other such case is or will be based on the sample;
e. The sampled article is perishable;
f. The sample is decomposed or otherwise unfit for analysis;
g. The part of the sample that will be destroyed is in excess of three times the quantity FDA estimates to be sufficient for analysis.

9. Can FDA use 702(b) portions of a sample for research purposes?

Yes, FDA may use an official sample, including the 702(b) portion, for research purposes, provided that the conditions for destruction under 21 CFR 2.10(e) are met. In such situations, because FDA has met the conditions for destruction, the owner is no longer entitled to the 702(b) portion of the sample.

10. How should the owner request a 702(b) portion?

The owner should send a request for the 702(b) portion of an official sample to the FDA Division[4] of the officer or employee who collected the sample. The request can be addressed to the Division's Director of Compliance.[5] The request for a 702(b) portion must be in writing (e.g., electronic mail or letter) and be accompanied by either a showing of ownership of the sample or the authority to receive the sample on behalf of the owner (21 CFR 2.10(c)). The request should also include relevant details regarding the sample (e.g., the lot, serial number, model number, or other identification of the sampled product). The owner who requests the 702(b) portion must specify the amount desired. (21 CFR 2.10(c)(2)). In addition to the request,

[4] FDA's Office of Regulatory Affairs (ORA) staff are assigned to program areas, where they specialize in a commodity. Each program area is organized by Divisions. See https://www.fda.gov/about-fda/office-regulatory-affairs/ora-program-division-boundary-maps-and-fact-sheets for more information.
[5] Contact information is available at https://www.fda.gov/about-fda/contact-ora/ora-field-leadership-contacts.

the owner should, if available, provide a copy of the Form FDA 484 Receipt for Samples issued by the collecting officer or employee to the responsible individual from whom the sample was collected to facilitate FDA's identification of the sample that was collected (see IOM, Chapter 4 for a copy of Form FDA 484).

In responding to the request, the FDA Division for the officer or employee who collected the sample may consult, as needed, with ORA's Office of Regulatory Science, FDA's Office of Chief Counsel, the appropriate FDA Center, the laboratory holding the 702(b) portion, as well as the Division in which the officer or employee is located, if different from the Division that collected the sample.