SLACK-FILL GUIDANCE

November 2016

Prepared by the American Herbal Products Association

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

Disclaimer

The information contained herein is not and should not be considered legal advice. This AHPA publication is not a substitute for the actual regulations that apply to the products and activities that are discussed herein. The information contained herein is not intended to replace or supersede FDA regulations or guidance.

This document is specifically relevant to addressing existing FDA slack-fill regulations. No other issues related to the manufacture, marketing, or sale of food, dietary ingredients or dietary supplements are addressed herein. This guidance does not have any direct application to packaging practices that may be deceptive that are not covered under 21 CFR 101.100.

While AHPA believes the information herein is accurate, any company that chooses to use this information is advised to discuss all aspects of their application of this information to specific packaging facts with an attorney, qualified consultant, or with relevant FDA staff.

Introduction and Statement of Purpose

The Food and Drug Administration (FDA) regulates how food (including dietary supplement) containers are filled to prevent the use of partially filled or oversized containers that could mislead consumers about the actual quantity of food they are purchasing. The difference between the actual capacity of a container and the volume of product inside is called "slack-fill." FDA promulgated the final slack-fill rule in 1994 to "remedy the inadequate implementation" of the federal law concerning food containers that may mislead consumers. FDA clarified that the rulemaking "[was] not intended to authorize actions against companies that fill packages as full as practicable in compliance with good manufacturing practice."

The American Herbal Products Association (AHPA) created this guidance to assist manufacturers and packagers of food and dietary supplements, referred to collectively hereinafter as "companies," in complying with federal regulation concerning the slack-fill in food containers.

The current federal slack-fill regulation titled, Misleading Containers: Nonfunctional Slack-Fill, can be found in the most recent edition of Title 21 of the Code of Federal Regulations, Part 101.100. Companies should familiarize themselves with this regulation prior to reading this guidance.

This guidance is organized into three sections. The first section, "Slack-Fill Law, Regulation & Litigation," provides legal and regulatory background. The second section, "Is the Slack-Fill Functional?" discusses the rule and the enumerated exemptions in detail to provide practical considerations for packagers of food and dietary supplement products, and the third section, "Practical Considerations," provides basic questions for a company to consider to help a company comply with federal slack-fill regulation.

Section 1: Slack-Fill Law, Regulation and Litigation

Federal Law and Regulation

On January 5, 1994, FDA issued the final rule entitled, *Misleading Containers: Nonfunctional Slack-Fill* (final Rule) to implement section 403(d) of the Food, Drug, and Cosmetic Act (FD&CA)[1] as required by the 1990 National Uniform Labeling Act amendments.[2] Federal law provides that "[a] food [or dietary supplement] shall be deemed to be misbranded if its container is so made, formed, or filled to be misleading."[3] The final Rule provides that a container is presumptively misleading if (1) it does not allow consumers to fully view the contents therein, and (2) it contains nonfunctional slack-fill.[4]

The final Rule defines "nonfunctional slack-fill" as the empty space in a container filled to less than its capacity for reasons other than the enumerated exemptions for empty space necessary to serve a specific function related to the product or packaging.[5] If one or more of exemption applies, the empty space in the food container is considered "functional" and not, therefore, not misleading.

When is slack-fill "misleading"?

There are no hard and fast rules as to when slack-fill *is* misleading. Generally, federal law provides specific examples of when slack-fill *is not* misleading.[6] However, FDA does explain that "[s]lack-fill whose only function is to make the product container larger, and thus to mislead the consumer as to the quantity of food in the container, is nonfunctional slack-fill and, therefore, misleading."[7]

It must be noted that whether or not fill is misleading does not require proving intent to mislead the consumer.[8] Therefore, slack-fill may still be misleading, regardless of a company's intent if a reasonable consumer would be misled as to the amount of product in the in container.[9]

FDA enforcement

Despite FDA authority to enforce the provisions concerning misbranded food and dietary supplements, most actions taken for alleged slack-fill violations have been through private enforcement via class action lawsuits.

[1] Public Law 75-717, 52 Stat. 1040 (January 25, 1938)
[2] 58 FR 64123-24
[3] FD&CA §403(d); 21 CFR 100.100(a)
[4] 21 CFR 100.100
[5] 21 CFR 100.100
[6] 21 CFR 100.100; 58 FR 64128; 58 FR 64136
[7] 58 FR 64127-28
[8] 58 FR 64128
[9] 58 FR 64128

State regulation

Federal law expressly preempts any state slack-fill regulation not identical to federal slack-fill regulation.[10] However, states may still enforce state slack-fill regulations identical to 21 CFR 100.100.[11]

Litigation

While federal law preempts enforcement of state slack-fill regulations not identical to the federal regulation, nothing preempts the use of other state laws that enable consumers to sue companies that label or package their products in violation of federal standards.

In 2015, several conventional food and dietary supplement companies faced slack-fill litigation brought by a handful of class action attorneys in California, New York, and Washington, DC. In addition to alleging violations of federal slack-fill law, the attorneys used state consumer protection and unfair and deceptive acts and practices (UDAP) statutes, and common law claims such as negligent misrepresentation and fraud to expand the claims.

[10] FD&CA §403A(a)(3); 58 FR 64125

[11] FD&CA §403A(a)(3); California Fair Packaging and Labeling Act, SB 465 (September 30, 2013). In 2013, California, revised its slack-fill regulation to provide that California's regulation is only operative to the extent that is identical to federal slack-fill regulation

Section 2: Is the Slack-Fill Functional?

How Much Empty Space Is Too Much?

The amount of slack-fill is a function of the size of the container and the volume of the fill.[12] The amount (i.e., numerical value) of empty space is not, however, FDA's primary consideration in determining whether there is too much empty space in a container.[13] Their primary consideration is whether the empty space is functional.[14] The amount of empty space comes into play only in determining how much space is needed to accomplish a specific function.[15]

Are there allowances for "normal variations"?

Yes. In the preamble to the final Rule, FDA states that normal variations in the level of fill are excluded from the definition of nonfunctional slack-fill.[16] This exclusion is not, however, a catchall. FDA narrowly interprets section 403(d) as allowing only "normal variations in fill based on the characteristics of a particular product or the capabilities of machines used to fill packages."[17]

Container size

The empty space in a filled container not necessary to accomplish a specific enumerated function may be deemed nonfunctional and, therefore, misleading.[18] As such, an appropriately sized container for amount of product sold in that unit can decrease the amount of empty space in a container that could be deemed nonfunctional. Factors that affect the choice of container size such as marketing data, cost, and handling and distribution requirements are alone insufficient to deem the empty space functional and, therefore, not misleading.[19]

Container shapes

Generally, the final Rule does not cover container shapes because the shape relates to how a container was "made" or "formed," not "filled" and FDA determined that the "made" and "formed" provisions of 403(d) were sufficiently straightforward as to be self-implementing.[20] However, to the extent that the shape of a container results in slack-fill, such slack-fill may serve an enumerated function outlined in the final Rule and, therefore, not be misleading under section 403(d).[21]

Can the Consumer 'Fully View' the Contents?

A container that enables consumers to fully view its contents is presumed not to be filled as to mislead.[22] "Fully view" means consumers can clearly see the amount of product inside and,

[12] 21 CFR 100.100
[13] 58 FR 641335
[14] 58 FR 641335
[15] 58 FR 64126
[16] 58 FR 64135
[17] 58 FR 64135
[18] 21 CFR 100.100
[19] 58 FR 64130
[20] 58 FR 64125 & 34
[21] 58 FR 64134
[22] 58 FR 64128

consequently, could not be misled about the amount of product they are purchasing.[23] This presumption applies to containers such as a glass jar, clear plastic bottle, or a clear poly bag.[24] This presumption does not apply to containers that must be held up to light to see the contents or that have labeling or graphics that obscure the full view of the contents.[25]

Use of transparent panels and windows

The entire container need not be transparent.[26] FDA states that it may be sufficient that the container has a transparent feature (e.g., a lid or panel).[27] The transparent feature can be on the side or top of the container, provided that such a feature does not require consumers to manipulate the container to fully view the contents.[28] FDA adds that including a clear and conspicuous statement about the feature on the front of the label may help assure that consumers see the feature and are not misled about the amount of product in the container.[29]

Label statements and fill lines

FDA asserts that label statements, including fill lines, may not be used to inform consumers about and, therefore, remedy the presence of *nonfunctional slack-fill.*[30] FDA notes specifically that net weight statements do not provide protection against misleading fill.[31]

Label statements on containers with *functional slack-fill* are permitted to inform consumers about how much product they are actually getting.[32] For example, a statement such as, "Contents may settle during shipping," is acceptable to alert consumers as to the presence of functional slack-fill and provide information about the function of that empty space.[33]

Functional Slack-Fill Exemptions

As discussed above, the final Rule provides that a container is nonfunctional and, therefore, misleading if it does not allow consumers to fully view its contents and is filled to less than its capacity for reasons other than:

1. Protection of the contents of the package;
2. The requirements of the machines used for enclosing the contents in such package;
3. Unavoidable product settling during shipping and handling;
4. The need for the package to perform a specific function (e.g., where packaging plays a role in the preparation or consumption of a food) where such function is inherent to the nature of the food and is clearly communicated to consumers;

[23] 58 FR 64128
[24] 58 FR 64128
[25] 58 FR 64128
[26] 58 FR 64128
[27] 58 FR 64128
[28] 58 FR 64128
[29] 58 FR 64134; For more information on required statements see below discussion of 21 CFR 100.100(a)(4)
[30] 58 FR 64129
[31] 58 FR 64128
[32] 58 FR 64128-29
[33] 58 FR 64129

5. The fact that the product consists of a food packaged in a reusable container where the container is part of the presentation of the food and has value which is both significant in proportion to the value of the product and independent of its function to hold the food; or
6. Inability to increase level of fill or to further reduce the size of the package to accommodate required food labeling, discourage pilfering, facilitate handling, or accommodate tamper-resistant devices.[34]

Conversely, if a container is filled to less than capacity for one of the aforementioned reasons, it is functional and, therefore, not misleading.

The applicability of each exemption turns on whether the empty space in a container serves the specific function, and whether that function relates to the product or the materials, processes, and equipment necessary to put the product in the container.[35] For example, an oversized lid that functions as a measuring device for the product may fall within an exemption, but an oversized lid used only to improve shelf-presence would not. FDA suggests that companies know the physical characteristics of their products and the capabilities of their packaging equipment to ensure that any slack-fill in their packages performs one or more valid functions and is, therefore, not misleading.[36]

Protection of the contents of the package (21 CFR 100.100(a)(1))

The empty space necessary to protect the contents of the package is functional slack-fill.[37] To determine whether the empty space is "necessary," a company should understand how the physical characteristics of the product and packaging materials, and the shipping and holding procedures and conditions may affect the product.[38] Examples of space necessary for the protection of the contents include the empty space required to prevent breakage during shipping and handling[39] and the headspace in a container filled with nitrogen to protect the product from oxidation.[40]

Requirements for the machine used for enclosing the contents in such package (21 CFR 100.100(a)(2))

The slack-fill necessary for the efficient functioning of equipment used to enclose a product in its immediate container is functional slack-fill provided that the company makes appropriate use of available packaging materials and filling equipment.[41] FDA interprets this exemption to apply only to the requirements of the equipment used to put the product in the immediate container (e.g., filling and sealing equipment).[42] This exemption does not apply to the requirements of all equipment used in the manufacture, distribution, and sale of the product.[43]

To make "appropriate use" of available packaging materials and filling equipment a company should select and use packaging materials and equipment to ensure that containers are filled as full as

[34] 21 CFR 100.100(a)(1)-(6)
[35] 58 FR 64132
[36] 58 FR 64128
[37] 22 CFR 100.100(a)(1)
[38] 58 FR 64127
[39] 58 FR 64129
[40] 58 FR 64128
[41] 58 FR 64131-32
[42] 58 FR 64132
[43] 58 FR 64132

practicable.[44] Compliance with the final Rule does not require companies operating under the applicable current good manufacturing practice to change the physical characteristics of a food or purchase additional or more sophisticated packaging equipment."[45]

Unavoidable product settling during shipping and handling (21 CFR 100.100(a)(3))

To the extent the physical characteristics of a product and the limitations of the filling equipment contribute to unavoidable product settling during shipping and handling, such slack-fill is functional and, therefore, not misleading.[46] Product settling is "unavoidable" when a company uses available packaging equipment in a manner that encourages product settling during the packaging process, or makes appropriate use of packaging materials and equipment, yet the characteristics of the product or the capabilities of packaging equipment still result in product settling during shipping and handling.[47]

The need for packaging to perform a specific function inherent to the nature of the food (21 CFR 100.100(a)(4))

Slack-fill that results from the need for the package to perform a specific function is not misleading if the specific function is inherent to the nature of the product and the function is obvious or clearly communicated to consumers.[48] For example, specific package functions inherent to the nature of the food includes packaging that can be used to prepare or consume the food.[49] Any space in excess of the space necessary to serve the specific function is deemed nonfunctional and, therefore, misleading.[50]

The final Rule provides that the specific function of the packaging must be clearly communicated to the consumer unless such function is obvious (e.g., a bowl-shaped food package that can be used to consume the food after adding water or milk).[51] In the preamble to the final Rule, FDA explains that a function is obvious when packaging enables consumers to "clearly see the amount of product relative to the other packaging components."[52] Examples of obvious functions include single-serving multipacks of pudding in an open-ended sleeve, or a box with single-serving meal replacement packets and a shaker cup, provided that the box is designed to display the single-serving packets and cup.[53] As with all required label information, the information about the function of the packaging, if required, must be prominently placed on the label or labeling "with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."[54]

[44] 58 FR 64129 & 32
[45] 58 FR 64129
[46] 58 FR 64127
[47] 58 FR 64127. For more on "appropriate use" see above discussion of 21 CFR 100.100(a)(2)
[48] 58 FR 64133
[49] 21 CFR 100.100(a)(4)
[50] 58 FR 64127
[51] 21 CFR 100.100(a)(4)
[52] 58 FR 64133
[53] 58 FR 64133
[54] 58 FR 64134

Reusable container of independent and significant value (21 CFR 100.100(a)(5))

The empty space in a container is functional slack-fill if the container is reusable, part of the presentation of the food, and has value that is both significant in proportion to the value of the product and independent of its function to hold the food (e.g., a container intended for further use after the food or supplement is consumed, or durable commemorative or promotional packaging).[55]

The nature of the container (i.e., whether it is reusable or valuable) can be a factor but does not alone determine whether an exemption applies.[56] Companies must consider the nature of the container in the context of the consumers' ability to make "appropriate value comparisons based on their perception of the quality and quantity of food in a container."[57]

Inability to increase level of fill or to further reduce the size of the package (21 CFR 100.100(a)(6))

Empty space that results from the inability to increase level of fill or to further reduce the size of the package is functional slack-fill.[58] This includes when a larger package size is necessary to accommodate mandatory food labeling, discourage pilfering, facilitate handling, or accommodate tamper-resistant devices.[59]

FDA advises that if a company is unable to increase the fill level or further reduce the size of the package, manufacturers and retailers can devise systems to facilitate product handling that allow the product to be packaged in a container whose size clearly communicates the amount of product inside.[60]

Additional expressed exemptions

In addition to the safe harbors discussed above, FDA expressly states that slack-fill necessary for the following reasons are also exempted: presence of measuring devices or prizes in a container, liquid products that have cooled after being packaged hot, ability to reclose the package, and the need to accommodate devices that reduce the risk of microbiological and filth contamination.[61]

[55] 21 CFR 100.100(a)(5)
[56] 58 FR 64133
[57] 58 FR 64133
[58] 21 CFR 100.100(a)(6)
[59] 21 CFR 100.100(a)(6)
[60] 58 FR 64130. For further discussion on how to clearly communicate the amount of product see above discussion of 21 CFR 100.100(a)(4)
[61] 58 FR 64136

Section 3: Practical Considerations

Primary Considerations

Manufacturers must know and understand the physical characteristics of their products and packaging materials, and the capabilities of their packaging equipment, to ensure that any slack-fill in their packages is there to perform one or more specific functions enumerated in an exemption. A company that determines that the empty space in a product container is not misleading should create, maintain, and be prepared to provide, documentary support for their conclusion.

The following are basic questions a company can consider to help comply with federal slack-fill regulation. AHPA does not purport the list to be exhaustive and strongly advises companies to discuss all aspects of related subject matter with an attorney, qualified consultant, or with relevant FDA staff.

Size of container

- Is the container size appropriate for the amount of product sold in that unit?
- Would the average consumer expect to find more product in the container?

Container shapes

- Does the container shape affect the fill level?
  - If yes,
    - Does an enumerated exemption apply?

Can the consumer "fully view" the contents?

- Is the container made from such materials that consumers can clearly see the amount of product they are purchasing?
- Is the container constructed in such a way that consumers can clearly see the amount of product they are purchasing?
- Could an average consumer under normal conditions of use be misled about the amount of product in the container?

Label statements

- Does the label statement relate to the presence of *functional slack-fill*?
- Is the label statement used to help consumers know how much product they are actually getting or to explain the function of the *functional slack-fill*?

Does a Slack Fill Exemption Apply?

General considerations

- Does the empty space in the container serve a function outlined in an enumerated exemption?
- Does the empty space in the container serve the specific function as it relates to the product, or the materials, processes, and equipment necessary to put that product in the immediate container?

Protection of the contents of the package (21 CFR 100.100(a)(1))

- Does the empty space in the container result directly from the protection of the package contents?
    - If yes, the space be attributed to the protection of the package contents?

Requirements for the machine used for enclosing the contents in such package (21 CFR 100.100(a)(2))

- Does the function apply to the requirements the equipment used to put the product in the container (e.g., filling and sealing equipment)?
- Have the available packaging materials and equipment been appropriately selected and utilized to minimize nonfunctional slack-fill?
- Are there practicable changes or adjustments you can make to packaging materials or equipment to minimize nonfunctional empty space?

Unavoidable product settling during shipping and handling (21 CFR 100.100(a)(3))

- Was the available packaging equipment used in a manner that encourages product settling during the packaging process?
- Were the characteristics of the product or the capabilities of packaging equipment that may result in slack-fill from product settling during shipping and handling accounted for?

The need for packaging to perform a specific function (21 CFR 100.100(a)(4))

- Is the packaging necessary to serve a specific function?
- Is that function inherent to the nature of the food?
- Is the function obvious to a reasonable consumer?
    - If no, is the function clearly and conspicuously communicated to the consumer?

Reusable container of significant value (21 CFR 100.100(a)(5))

- Is the container:
    - Reusable?
    - Part of the presentation of the food?
    - Of value significant in proportion to the value of the product?
    - Of value independent of its function to hold the food?

Inability to increase level of fill or to further reduce the size of the package (21 CFR 100.100(a)(6))

- Can the level of fill be increased or the size of the package further reduced?
    - If no, are there practicable alternatives to address the reason for which the fill cannot be further increased or the size of the package further reduced?
        - If no, does the packaging used clearly communicate to the consumer the actual amount of product in the container?