

SLACK-FILL GUIDANCE

January 2019 (Revised)

Prepared by the American Herbal Products Association



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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 § 100.100.

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.

This document was originally published in November 2016 under the same title. It has been reorganized and edited for clarity, with one substantive revision in the discussion on “Label statements and fill lines” in section 2.2.2. In addition, more attention is provided in this update to several somewhat obscure regulatory exemptions, as identified in section 1.1.3.7., and two appendices have been added to provide additional relevant information. This document is the property of the American Herbal Products Association (AHPA) and is for AHPA purposes only. Unless given prior approval from AHPA, it shall not be reproduced, circulated, or quoted, in whole or in part, outside of AHPA, its Committees, and its members. Cite as: American Herbal Products Association. January 2019. Slack-Fill Guidance (Revised). AHPA: Silver Spring, MD.

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Introduction and Statement of Purpose

The Food and Drug Administration (FDA or the Agency) 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 a final slack-fill rule in 1993 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 in complying with federal regulations concerning the slack-fill in food containers.

The current federal slack-fill regulation is titled “Misleading containers” and can be found in the most recent edition of Title 21 of the Code of Federal Regulations, Section 100.100 (21 CFR § 100.100). Companies should familiarize themselves with this 1-page regulation prior to reading this guidance.

This guidance is organized into three sections. The first section, “Slack-Fill Law, Regulation and Enforcement,” provides legal and regulatory background, including details on regulatory exemptions to the definition of “nonfunctional slack-fill.” The second section, “Is the Slack-Fill Functional?,” discusses the rule in detail with particular attention to the key issues of the amount of empty space in a container and how the quantity of the contents of a food package are communicated to the consumer, and the third section, “Practical Considerations,” provides basic questions for a packager of food and dietary supplement products to consider to evaluate compliance with federal slack-fill regulations.

Section 1: Slack-Fill Law, Regulation and Enforcement

1.1 Federal Law and Regulation

1.1.1 Statutory Background

The Nutrition Labeling and Education Act of 1990 (NLEA) amended the Food, Drug and Cosmetic Act (FDCA or the Act) in numerous ways. Section 6 of NLEA, titled “National Uniform Nutrition Labeling,” establishes federal preemption on many elements of food labeling. This has the effect of prohibiting states from establishing and enforcing requirements that differ from federal requirements on these specified elements, including the misbranding provision of the Act that covers misleading containers. This provision is found in section 403(d) of the Act, 21 USC § 343(d), and it declares that a food is misbranded “[i]f its container is so made, formed, or filled as to be misleading.”¹ Because dietary supplements are regulated as foods for most purposes,² this misbranding provision also applies to containers in which supplement products are packaged.³

In addressing compliance dates for the federal preemption provisions included in NLEA, Congress instructed the Secretary of Health and Human Services, and by delegation FDA, to have a study conducted to determine if current federal regulations “adequately implement the purposes” of the relevant sections of labeling law. In so doing, Congress acknowledged that “a strong Federal regulatory system must be in place before State laws are preempted.”⁴ FDA subsequently determined that section 403(d) of the Act, i.e., the misleading containers provision, was “not adequately being implemented”⁵ and so initiated rulemaking for this matter, as described below.

1.1.2 Implementing Regulations

In a Federal Register notice published on December 6, 1993, and titled “Misleading Containers; Nonfunctional Slack-Fill” (the 1993 Notice; attached here in its entirety as Appendix 1), FDA issued a final rule to implement section 403(d) of the Act, in which the Agency “sets out the circumstances in which the slack-fill within a package is nonfunctional and, therefore, misleading.”⁶

The final rule, codified as 21 CFR § 100.100, and titled “Misleading containers” (the FDA slack-fill rule), provides that a food container that “does not allow the consumer to fully view its contents shall be considered to be filled as to be misleading” (and thus misbranded under section 403(d) of the Act) if it contains “nonfunctional slack-fill.”⁷ In its preamble to the final rule, FDA also notes that “nonmisleading

¹ FDCA § 403(d), 21 USC § 343(d).

² FDCA § 201(ff)(3), 21 USC § 321(ff)(3).

³ 58 FR 64123, 64134 (Dec. 6, 1993).

⁴ 58 FR at 64124 (citing 136 Cong. Rec. H5842 (July 30, 1990)).

⁵ 58 FR 2470, 2472 (Jan. 6, 1993).

⁶ 58 FR at 64123. The Agency subsequently published a separate Federal Register notice on January 5, 1994, to revoke a regulation on the same matter that had become a final rule by operation of law on May 10, 1993, and to replace the revoked rule with the final rule that was published on December 6, 1993. 59 FR 536, 537 (Jan. 5, 1994).

⁷ 21 CFR § 100.100(a).

containers are those that are filled as full as practicable.”⁸ The FDA slack-fill rule defines “slack-fill” as “the difference between the actual capacity of a container and the volume of product contained therein,” and defines “nonfunctional slack-fill” as “the empty space in a package that is filled to less than its capacity” for reasons other than several specifically enumerated exemptions,⁹ which are presented below and described herein as “functional slack-fill.” If one or more of these exemptions applies to a food or supplement container, the empty space in the container is considered “functional” and therefore not misleading.

1.1.3 Functional Slack-Fill Exemptions

The FDA slack-fill rule identifies six specific reasons why the empty space in a package that is filled to less than its capacity is not considered to be nonfunctional. These reasons are specified in the following subparagraphs of 21 CFR § 100.100(a):

- (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;
- (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, e.g., a gift product consisting of a food or foods combined with a container that is intended for further use after the food is consumed; or durable commemorative or promotional packages; or
- (6). Inability to increase level of fill or to further reduce the size of the package (e.g., where some minimum package size is necessary to accommodate required food labeling (excluding any vignettes or other nonmandatory designs or label information), discourage pilfering, facilitate handling, or accommodate tamper-resistant devices).

If a container is filled to less than capacity for one or more of the above functional slack-fill reasons, the slack-fill would qualify as “functional,” the container would not qualify as misleadingly filled, and the presence of the slack-fill would not render the product misbranded under the Act. The 1993 Notice’s preamble also indicates that slack-fill included for additional reasons, not included in the codified text but referenced below, would qualify as “functional” and therefore not render the product misbranded. FDA notes, however, that slack-fill in excess of the amount necessary to accomplish a particular function is nonfunctional (i.e., misleading) slack-fill.¹⁰

The applicability of each exemption turns on whether the empty space in a container serves the specific function, and whether the amount of slack-fill present is necessary to achieve that function. FDA suggests that companies know the physical characteristics of their products and the capabilities of their

⁸ 58 FR at 64128.

⁹ 21 CFR § 100.100(a).

¹⁰ 58 FR at 64127.

packaging equipment to ensure that any slack-fill in their packages performs one or more valid functions and is, therefore, not misleading.¹¹

1.1.3.1 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.¹² To determine whether the empty space is necessary, for this purpose, 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. Examples of space necessary for the protection of the contents include the headspace in a container filled with nitrogen to protect the product from oxidation,¹³ and could also include the empty space required to prevent breakage during shipping and handling, such as the space needed to insert a cotton or rayon space filler in a bottle of tablets to prevent breakage or to protect the tablet coating.

1.1.3.2 Requirements of the machines 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.”¹⁴ This exemption is applicable not only to the requirements of the specific machine used to fill the product into the container but to also cover “all equipment involved when product and package come together,” including, as one example, the equipment used to fill package headspace with nitrogen.¹⁵ In summary, the slack-fill necessary “for the efficient functioning of the machines used to enclose the contents in a package” is functional slack-fill.¹⁶

Of additional relevance to this specific exemption, compliance with the FDA slack-fill rule does not require companies “operating under [the applicable] current good manufacturing practice to change the physical characteristics of a food . . . [or] to purchase additional or more sophisticated packaging equipment,” and FDA recognizes that this exemption covers “the use of a single filling machine to package related products when such use is appropriate.”¹⁷

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

To the extent the physical characteristics of a product (e.g., particle size and shape, product density, and product fragility) 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. 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

¹¹ 58 FR at 64128.

¹² 21 CFR § 100.100(a)(1).

¹³ 58 FR at 64132.

¹⁴ 58 FR at 64131.

¹⁵ 58 FR at 64132.

¹⁶ 58 FR at 64132.

¹⁷ 58 FR at 64129.

equipment, yet the characteristics of the product or the capabilities of packaging equipment still result in product settling during shipping and handling.¹⁸

At the same time, this exemption would obviously not apply to a company's adjusting line speed and use of filling equipment to intentionally ensure that a product is more loosely packed than necessary in order to "temporarily achieve what appears to be a full container," and such a procedure would not constitute functional slack-fill under section 100.100(a)(3).¹⁹

1.1.3.4 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. Specific package functions inherent to the nature of the food include packaging that can be used to prepare or consume the food.²⁰

21 CFR § 100.100(a)(4) provides that the specific function of the packaging must be clearly communicated to the consumer, except that when the function of this functional slack-fill is obvious (e.g., a bowl-shaped food package that can be used to consume the food) it is "not necessary to provide a label statement declaring the obvious."²¹ FDA provides several examples of packaging that enables consumers to "clearly see the amount of product relative to [the] other [packaging] components," including 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.²²

Because this particular exemption addresses the issue of communicating material information to consumers, as with all required label information, any required information about the function of the packaging 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.'"²³ At the same time, FDA has to date refrained from establishing specific requirements for type size or placement of statements related to the function of slack-fill within a container.²⁴

1.1.3.5 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

¹⁸ 58 FR at 64127.

¹⁹ 58 FR at 64127.

²⁰ 21 CFR § 100.100(a)(4).

²¹ 58 FR at 64133.

²² 58 FR at 64133.

²³ 58 FR at 64134.

²⁴ See, e.g., 58 FR at 64134.

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).²⁵

The nature of the container (i.e., whether it is reusable or valuable) can be a factor but does not alone determine whether the exemption applies.²⁶ In evaluating the applicability of this exemption, 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."²⁷

1.1.3.6 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 the level of fill or to further reduce the size of the package is functional slack-fill. This includes when a larger package size is necessary to accommodate mandatory food labeling, discourage pilfering, facilitate handling, or accommodate tamper-resistant devices.²⁸

FDA advises that manufacturers relying on this exception should be prepared to demonstrate that "the level of fill is appropriate for the particular product, and that package size cannot be further reduced."²⁹

1.1.3.7 Additional exemptions recognized by FDA

In addition to the exemptions included in the codified regulation at 21 CFR § 100.100(a)(1) to (a)(6) discussed above, FDA expressly stated in the 1993 Notice that slack-fill necessary for the following reasons "is also exempted" from the definition of nonfunctional slack-fill and so would not qualify a container as misleadingly filled: (i) the presence of measuring devices or prizes in a container; (ii) liquid products that have cooled after being packaged hot; (iii) the ability to reclose the package, and (iv) the need to accommodate devices that reduce the risk of microbiological and filth contamination.³⁰ While these exemptions do not appear in the codified regulation, a company could reasonably rely on FDA's preamble statements and cite them in defending against an allegation that slack-fill present for any of these reasons does not qualify as "functional."

1.1.4 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.³¹ However, FDA does explain that "the appropriate test is whether or not the empty space within a package performs a specific function in relation to the product or its packaging" and that "[s]lack-fill whose only function is to make the product container larger, and thus to deceive the consumer as to the quantity of food in the container, is nonfunctional

²⁵ 21 CFR § 100.100(a)(5).

²⁶ 58 FR at 64133.

²⁷ 58 FR at 64133.

²⁸ 21 CFR § 100.100(a)(6).

²⁹ 58 FR at 64130.

³⁰ 58 FR at 64136.

³¹ 21 CFR § 100.100; 58 FR at 64128, 64136.

slack-fill and, therefore, misleading.”³² The Agency further states that “it is incumbent on manufacturers, knowing the physical characteristics of their products and the capabilities of their packaging equipment, to ensure that any slack-fill in their packages is there to perform one or more valid functions.”³³

It must be noted that whether or not slack-fill is misleading does not require proving intent to mislead the consumer.³⁴ 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 container.

1.2 Enforcement

1.2.1 FDA enforcement

Despite FDA authority to enforce the provisions concerning misbranded food and dietary supplements, including the misleading containers rule, most actions taken for alleged slack-fill violations have been through private enforcement via class action lawsuits. For example, using available databases during the revision of the present document (i.e., October-November 2018), AHPA has not identified a single FDA warning letter alleging a violation of 21 CFR § 100.100.

1.2.2 State regulation

The Act as amended by NLEA expressly preempts any state slack-fill regulation not identical to the federal slack-fill regulation.³⁵ However, states may still enforce state slack-fill regulations identical to 21 CFR § 100.100.³⁶ For example, California officials have prosecuted alleged violations of the state’s slack-fill law.³⁷

1.2.3 Private 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. Attention by private plaintiffs has continued since, and reports have been published in the trade press that suggest that many private complaints result in

³² 58 FR at 64128.

³³ 58 FR 64128.

³⁴ 58 FR at 64128.

³⁵ FDCA § 403A(a)(3), 21 USC § 343-1(a)(3); 58 FR at 64125.

³⁶ FDCA § 403A(a)(3), 21 USC § 343-1(a)(3).

³⁷ See Cal. Bus. & Prof. Code § 12606.2.

settlements that are maintained as confidential.³⁸ See the attached Appendix 2 with a sample of reported court decisions and pending slack-fill complaints issued or filed in 2017 and 2018.

³⁸ Elaine Watson, *Food litigation 101: Nonfunctional slack fill . . . are you up to speed?* Food Navigator USA.com (Aug. 10, 2017). Accessed Oct. 10, 2018 at <https://www.foodnavigator-usa.com/Article/2017/08/11/Food-litigation-101-Non-functional-slack-fill-are-you-up-to-speed>.

Section 2: Is the Slack-Fill Functional?

2.1 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.³⁹ 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.⁴⁰ The Agency's primary consideration is whether the empty space is functional,⁴¹ and FDA states in the 1993 Notice that "slack-fill is justified when it performs a necessary function in a packaged food product."⁴² The amount of empty space comes into play only in determining how much space is needed to accomplish a specific function.⁴³

2.1.1 Are there allowances for "normal variations"?

Yes. In the preamble to the final FDA slack-fill rule, FDA states that "normal variations" in the level of fill are excluded from the definition of nonfunctional slack-fill.⁴⁴ This exclusion is not, however, a catchall. FDA narrowly interprets section 403(d) of the Act, that is, the misleading containers provision, as allowing only "normal variations in fill based on the characteristics of a particular product or the capabilities of machines used to fill packages."⁴⁵

2.1.2 Container size

The empty space in a filled container not necessary to accomplish a specific enumerated function may be deemed nonfunctional and, therefore, misleading.⁴⁶ As such, an appropriately sized container for the amount of product sold in that unit can decrease the amount of empty space that could be alleged as nonfunctional. Factors that affect the choice of container size such as marketing data, cost, and handling and distribution requirements are alone insufficient to qualify the empty space as functional and, therefore, not misleading.⁴⁷

2.1.3 Container shapes

Generally, the FDA slack-fill 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 section 403(d) of the Act were sufficiently straightforward so as to not require further

³⁹ 21 CFR § 100.100.

⁴⁰ 58 FR at 64135.

⁴¹ 58 FR at 64135.

⁴² 58 FR at 64127.

⁴³ 58 FR at 64126.

⁴⁴ 58 FR at 64135.

⁴⁵ 58 FR at 64135.

⁴⁶ 21 CFR § 100.100.

⁴⁷ 58 FR at 64130.

elaboration through regulation.⁴⁸ On the other hand, a container made or formed to allow use of side walls and false bottoms, the only purpose of which is to create empty space (i.e., space devoid of product), would be clearly misleading.⁴⁹

2.2 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.⁵⁰ “Fully view” means consumers can clearly see the amount of product inside and, consequently, consumers could not be misled about the amount of product they are purchasing.⁵¹ This presumption applies to containers such as a glass jar, a clear plastic bottle, or a clear poly bag.⁵² 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.⁵³

2.2.1 Use of transparent panels and windows

The entire container need not be transparent.⁵⁴ FDA states that it may be sufficient that the container has a transparent feature (e.g., a lid or panel).⁵⁵ 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.⁵⁶ 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.⁵⁷

2.2.2 Label statements and fill lines

In its discussion of non-misleading, nonfunctional slack-fill in the 1993 Notice, FDA noted that it received the following comment: “. . . [I]f consumers can be informed of any level of slack-fill within the package, through label statements, pictorials, or other devices, they cannot be deceived as to the fill of the container.”⁵⁸

⁴⁸ 58 FR at 64125-26.

⁴⁹ 58 FR at 64126.

⁵⁰ 58 FR at 64128.

⁵¹ 58 FR at 64128.

⁵² 58 FR at 64128.

⁵³ 58 FR at 64128.

⁵⁴ 58 FR at 64128.

⁵⁵ 58 FR at 64128.

⁵⁶ 58 FR at 64128.

⁵⁷ 58 FR at 64134.

⁵⁸ 58 FR at 64127.

FDA disagreed and asserted that label statements may not be used to inform consumers about and, therefore, remedy the presence of *nonfunctional slack-fill*.⁵⁹ FDA noted specifically that net weight statements do not provide protection against misleading fill.⁶⁰

The Agency went on to say that label statements on containers with *functional slack-fill* are permitted to inform consumers about the presence and function of the slack-fill, which may reduce consumer dissatisfaction.⁶¹ For example, a statement such as, “Contents may settle during shipping,” is acceptable to alert consumers to the presence of functional slack-fill and provide information about the function of that empty space.⁶²

FDA's position on label statements is largely focused on statements of weight, volume and quantity and statements explaining the presence and cause of functional slack-fill.⁶³ While FDA clearly states that such label statements cannot correct nonfunctional or misleading slack-fill,⁶⁴ the Agency did not address whether label pictorials or other devices such as fill lines (as potentially distinguishable from “label statements” and referenced in the above-quoted comment) could remedy the presence of nonfunctional slack-fill.

Inclusion of a conspicuous fill line that allows the consumer to readily understand the level of product fill appears to achieve the same result as a transparent container—it ensures a consumer could not be misled as to the level of fill. (FDA's position is that a container that enables a consumer to fully view its contents is not misleading *because the consumer could not be misled as to the level of fill*.)⁶⁵ Given the above, manufacturers might consider using clear and conspicuous fill lines to alert consumers to the level of product fill—particularly where the packaging is not transparent enough to allow the consumer a full view of the contents.

Use of such a fill line may not deter FDA, another enforcement agency, or a private litigant from bringing an action alleging that a package contains misleading, nonfunctional slack-fill. And, in such an action, use of a conspicuous fill line may not provide as strong a defense as would reliance on one of FDA's above- and below-discussed regulatory exemptions. However, use of a fill line may provide a manufacturer a basis for defending as non-misleading a package that contains nonfunctional slack-fill.

⁵⁹ 58 FR at 64129.

⁶⁰ 58 FR at 64128.

⁶¹ 58 FR at 64129.

⁶² 58 FR at 64129.

⁶³ See 58 FR at 64128-29.

⁶⁴ 58 FR at 64129.

⁶⁵ 58 FR at 64128.

Section 3: Practical Considerations

3.1 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 21 CFR § 100.100(a)(1) to (a)(6) or otherwise described in the preamble of the 1993 Notice. They should also ensure that the amount of slack-fill present is no greater than necessary to achieve its purpose(s). 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 that conclusion.

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

3.1.1 Size of container

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

3.1.2 Container shapes

- Does the container shape affect the fill level? If so, does one of the exemptions enumerated in 21 CFR § 100.100(a)(1) to (a)(6) or referenced in the 1993 Notice's preamble apply?

3.1.3 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 purchase be misled about the amount of product in the container?

3.1.4 Label statements

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

3.2 Does a Functional Slack-Fill Exemption Apply?

3.2.1 General considerations

- 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?
- Does the empty space in the container serve a function outlined in an exemption enumerated in 21 CFR § 100.100(a)(1) to (a)(6) below or otherwise described in the preamble to the 1993 Notice?

3.2.2 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 so, can the space be attributed to the protection of the package contents?

3.2.3 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 of 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?

3.2.4 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?

3.2.5 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 not, is the function clearly and conspicuously communicated to the consumer?

3.2.6 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?

3.2.7 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 not, are there practicable alternatives to address the reason for which the fill cannot be further increased or the size of the package further reduced? And if not, does the packaging used clearly communicate to the consumer the actual amount of product in the container?

3.2.8 Does one of the additional reasons identified in the preamble to the final rule (i.e., in the 1993 Notice) apply?

- Is the container's slack-fill related to any of the following:
 - Presence of measuring devices or prizes in a container?
 - A liquid product that has cooled after being packaged hot?
 - Ability to reclose the package?
 - The need to accommodate devices that reduce the risk of microbiological and filth contamination

APPENDIX 1



Food and Drug Administration

21 CFR Part 100

[Docket Nos. 92N-0383 and 93N-0172]

Misleading Containers; Nonfunctional Slack-Fill

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting a regulation that implements section 403(d) of the Federal Food, Drug, and Cosmetic Act (the act) by defining the circumstances in which a food is misbranded under that section of the act. In particular, this regulation sets out the circumstances in which the slack-fill within a package is nonfunctional and, therefore, misleading. FDA is taking this action, in accordance with the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), to remedy the inadequate implementation of section 403(d) of the act. Elsewhere in this issue of the Federal Register, FDA is proposing to revoke a regulation implementing section 403(d) of the act that became final by operation of law.

DATES: Effective January 5, 1994, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5106.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 6, 1993 (58 FR 2957), FDA proposed to amend its regulations to define the circumstances in which a food is misbranded under section 403(d) of the act (21 U.S.C. 343(d)). The proposed rule, entitled "Misleading Containers; Nonfunctional Slack-Fill" (hereinafter referred to as the misleading container proposal), responded to the provisions of section 6 of the 1990 amendments (Pub. L. 101-535), entitled "National Uniform Nutrition Labeling," which added new section 403A to the act (21 U.S.C. 343-1). Section 403A(a)(3) of the act prohibits States from directly or indirectly establishing any requirement

for the labeling or packaging of any food in interstate commerce of the type required by section 403(b) (offered for sale under the name of another food), 403(d) (misleading container), 403(f) (appropriate prominence of information), 403(h) (standards of quality and fill), 403(i)(1) (common or usual name), or 403(k) (declaration of artificial flavoring, coloring, or preservatives) of the act that is not identical to the requirements of such sections. However, sections 6(b)(3) and 10(b)(1)(C) of the 1990 amendments provide that the six provisions listed in section 403A(a)(3) of the act do not become preemptive until FDA determines that each is being adequately implemented by Federal regulations.

In response to section 6(b)(3)(B) of the 1990 amendments, FDA published in the Federal Register of January 6, 1993 (58 FR 2470), final lists that identified which of the above six sections of the act that define circumstances in which a food is misbranded are (and are not) being adequately implemented by FDA's regulations. The agency concluded that sections 403(b), 403(f), 403(h), 403(i)(1), and 403(k) of the act are being adequately implemented, and that section 403(d) of the act is not being adequately implemented. The agency's determination that section 403(d) of the act is not being adequately implemented is discussed further in the final list (58 FR 2470 at 2472).

The 1990 amendments require that FDA propose revisions to its regulations for any section that the agency determines is not being adequately implemented (section 6(b)(3)(C) of the 1990 amendments). Thus, FDA published the misleading container proposal to amend its regulations to remedy the inadequate implementation of section 403(d) of the act. In the misleading container proposal, the agency proposed to create new § 100.100 *Misleading containers* (21 CFR 100.100) that would: (1) Repeat the misleading container provisions of section 403(d) of the act, and (2) define the circumstances in which the slack-fill within a package is nonfunctional and, therefore, misleading. FDA proposed to define "slack-fill" as the difference between the actual capacity of a container and the volume of product contained therein (proposed § 100.100(a)).

Interested persons were given until March 8, 1993, to comment. FDA received 20 letters, each containing one or more comments, from food manufacturers, trade organizations, State and local officials, a consumer, and a consumer interest group. Most comments generally supported the

proposed amendments. Many comments suggested modification of various provisions of the proposed rule or requested clarification of certain issues. A summary of the comments and the agency's responses are presented in section III. of this document.

II. Promulgation of Final Rule

Section 6(b)(3)(D)(ii) of the 1990 amendments provides that, if FDA does not issue final revisions to its regulations in accordance with section 6(b)(3)(C) within 30 months of the enactment of the 1990 amendments, the proposed revisions shall be considered the final revisions, and States and political subdivisions shall be preempted with respect to such revisions.

The 30-month period established by the 1990 amendments expired on May 8, 1993. Accordingly, FDA published a notice in the *Federal Register* of May 12, 1993 (58 FR 27932), announcing that the regulation that it proposed in the misleading container proposal is considered to be the final regulation by operation of law, effective May 10, 1993. The agency noted that the May 12, 1993, notice was part of a separate rulemaking contemplated by Congress if the agency did not issue final revisions by May 8, 1993, and that it bore a separate docket number (docket number 93N-0172) to distinguish it from the January 6, 1993, rulemaking, which was ongoing. FDA also stated in the May 12 notice that it intended to issue in the near future a final rule in the misleading container rulemaking that would supersede the regulation that is considered final by operation of law.

FDA is now issuing that final rule. The agency advises that the revisions to its regulations contained in this document take into consideration the comments that it received in response to the January 6, 1993, misleading container proposal. Therefore, FDA finds that this final rule is better able to ensure adequate implementation of section 403(d) of the act than the regulation that was considered final by operation of law but that did not have the benefit of a comment period. For this reason, elsewhere in this issue of the *Federal Register*, FDA is proposing to withdraw the regulation that is considered final by operation of law. Because FDA considers it unlikely that there will be any comment on that proposed action, the agency is providing that the version of § 100.100 that it is publishing in this final rule will become effective January 5, 1994, and supersede the regulation that became final by operation of law. If for any reason this will not be the case, FDA will publish

an appropriate notice in the *Federal Register*.

III. Comments to Proposal

A. Adequate Implementation

In the preamble to the proposed rule on misleading containers (58 FR 2957 at 2958) FDA advised that, should it receive evidence establishing that section 403(d) of the act is being adequately implemented, the agency would be willing to reconsider its contrary determination.

1. One comment maintained that section 403(d) of the act is being adequately implemented and urged that the agency reconsider the need for a regulation. In support of its position, the comment argued that the Fair Packaging and Labeling Act (the FPLA) gives no indication that Congress viewed FDA's implementation of section 403(d) of the act to be inadequate. The comment also maintained that the agency's earlier decision not to implement regulations under the FPLA was an appropriate response to the issue of slack-fill. The comment stated that fill of containers has rarely materially misled consumers. Finally, the comment argued that the potential benefits of expanded implementation of section 403(d) of the act, as proposed, will become even less needed in light of the agency's renewed emphasis on informative and conspicuous labeling.

As an alternative, the comment suggested that FDA establish a compliance policy guide (CPG) that affirms section 403(d) of the act by stating that misleading fill constitutes misbranding, and by listing the packaging considerations that FDA will use when assessing compliance with section 403(d). The comment stated that such a CPG should be sufficient to provide guidance to States that want to enforce or adopt Federal law.

Conversely, several comments stated that section 403(d) of the act has not been adequately implemented, and that further regulation of slack-fill is necessary: (1) To ensure adequate implementation of section 403(d) of the act, (2) to provide guidance to industry, and (3) to protect consumers. Comments provided examples of products that are on the market and, the comments asserted, are misleadingly filled.

FDA disagrees with the first comment. The comment misinterprets the agency's previous determination not to issue regulations defining "misleading fill" under the FPLA. The FPLA was promulgated, in part, to elaborate on and to reinforce the misbranding provisions in section 403 of the act. Section 2 (15 U.S.C. 1451) of the FPLA

declares that "Informed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons." Section 5(c)(4) of the FPLA (15 U.S.C. 1454(c)(4)) provides for the promulgation of regulations, whenever the promulgating authority determines that such regulations are necessary, to prevent the deception of consumers or to facilitate value comparisons of consumer commodities, including regulations to prevent nonfunctional slack-fill.

The agency's earlier decision not to promulgate, under the provisions of the FPLA, regulations implementing section 403(d) of the act was in relation to the efficient use of agency resources, not the adequate implementation of the intent of section 403(d). Based on a series of surveys in the 1970's on the incidence and function of slack-fill in consumer commodities (see 58 FR 2957 at 2959), FDA concluded that establishing specific limits on the level of slack-fill of consumer commodities, while authorized by the FPLA, would not be an appropriate way to expend its resources.

However, the 1990 amendments asked a different question. They directed FDA to examine the six sections of the act referred to in section 403A of the act, and the regulations issued by the Secretary to enforce those sections, to determine whether such sections and regulations adequately implement the purposes of such sections. In discussing the preemption provisions of the 1990 amendments, Congressman Waxman stated that a strong Federal regulatory system must be in place before State laws are preempted (136 Congressional Record H5842 (July 30, 1990)). Based on the agency's determination that section 403(d) of the act is not being adequately implemented (58 FR 2470 at 2472), FDA is compelled by the act to issue regulations on misleading containers, including misleading fill.

FDA also disagrees with the comment's argument that the potential benefits of expanded implementation of section 403(d) of the act will become even less necessary with FDA enforcement of the new nutrition labeling requirements. Although the agency expects to work closely with consumers and industry, especially during the transition to use of the new nutrition label, such interactions do not ensure adequate implementation of section 403(d) of the act. Section 403(d) of the act addresses a completely different aspect of how food is

presented than the nutrition label does. Further, as discussed in the final list document (58 FR 2470 at 2471), there is nothing in the act or in the legislative history of the 1990 amendments that indicates that level of enforcement should be a factor in determining adequacy of implementation. FDA concluded (58 FR 2470 at 2471) that it is appropriate to examine the regulations in place to implement each of the sections in question to determine whether each is being adequately implemented.

The first comment provided no evidence that section 403(d) of the act is being adequately implemented. Therefore, FDA concludes that there is no basis for the agency to reconsider its determination that section 403(d) of the act is not being adequately implemented.

FDA also finds no merit in the comment's suggestion that the agency establish a CPG on section 403(d) of the act. As noted above, section 6 of the 1990 amendments requires that FDA revise its regulations to ensure that there is adequate implementation of any of the six sections of the act that it determines is not being adequately implemented. FDA regulations adopted under section 701(a) of the act (21 U.S.C. 371(a)), after notice and comment rulemaking, have the force and effect of law. A CPG, on the other hand, is only a guideline. While guidelines establish principles or practices of general applicability that are acceptable to FDA for a matter that falls within the laws administered by the agency, they are not legal requirements. Because a CPG is not, by itself, legally binding, the agency finds that issuing one on misleading fill, as suggested by the comment, would not be an adequate response under section 6 of the 1990 amendments for ensuring adequate implementation of section 403(d) of the act. Therefore, FDA must reject this aspect of the comment.

Thus, FDA agrees with the comments that stated that section 403(d) of the act is not being adequately implemented, and that the adoption of a regulation is necessary.

B. Preemption Provisions of the 1990 Amendments

2. One comment stated that it supported "any amendment that would protect the consumer by further specifying the circumstances by which a package would be considered to be misbranded." However, the comment expressed concern that Federal preemption of State laws would reduce consumer protection from misleading containers and urged FDA to "allow both State and local officials the

opportunity to protect the consumer by not preempting State law."

FDA appreciates the concern expressed by the comment. However, in providing for national uniform nutrition labeling, section 6 of the 1990 amendments preempts any State or local requirement for the labeling or packaging of the type required by section 403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k) of the act that is not identical to the requirement of such section. The 1990 amendments provide that each of the six provisions listed in section 403A(a)(3) of the act become preemptive once FDA determines that the particular provision is being adequately implemented by Federal regulations or issues additional regulations necessary to ensure adequate implementation. Thus, FDA does not have the option to forgo preemption.

At the same time, the agency recognizes the traditional role of the States in protecting consumers against misleading packaging and filling practices. The agency expects that the States will continue their active role in this area under their own laws, where appropriate, and in cooperation with FDA under section 307 of the act (21 U.S.C. 337).

3. One comment stated that there should be no preemption unless FDA issues implementing regulations in the specific area covered by State or local law. Conversely, the comment maintained that States and localities are free to impose additional requirements within section 403(d) of the act if the Federal government has not spoken on certain specific issues.

FDA disagrees with this comment. Section 403A(a)(3) of the act states that no State or political subdivision of a State may directly or indirectly establish or continue in effect as to any food in interstate commerce " * * * any requirement of the type required by section 403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k) of the act that is not identical to the requirement of such section." Thus, under this provision, as explained more fully in the final rule entitled "State Petitions Requesting Exemption from Federal Preemption" (58 FR 2462, January 6, 1993), a State provision prohibiting misleading containers that is not identical to the requirements of section 403(d) of the act and to the provisions that FDA has adopted to implement that section would be preempted. As discussed in response to the previous comment, preemption is established as a matter of law by the 1990 amendments and to that extent is outside the control of FDA.

C. "Made" or "Formed" Provisions of Section 403(d) of the Act

Section 403(d) of the act states that a food is misbranded "if its container is so made, formed, or filled as to be misleading." Most of the discussion in a report submitted by the National Academy of Sciences, Institute of Medicine, Food and Nutrition Board (the IOM), and much of the information that the IOM received, regarding the adequacy of section 403(d) of the act centered around whether consumers are being adequately protected against slack-filled containers. Furthermore, of the States cited by the IOM that have established more specific requirements than section 403(d) of the act related to misleading containers, most have chosen to focus on misleading fill.

In concluding that section 403(d) of the act was not being adequately implemented, the IOM suggested that FDA consider promulgating regulations to prohibit misleading fill based on the definition of nonfunctional slack-fill provided for in the FPLA. The IOM did not recommend that the agency promulgate regulations with regard to the "made" or "formed" as to be misleading provisions of section 403(d) of the act.

Based on the IOM report and its review of the administrative record, FDA tentatively decided not to elaborate on ways in which a container may be made or formed as to be misleading. FDA tentatively concluded that these terms are straightforward and need little elaboration (58 FR 2957 at 2960). The agency invited comment on its tentative conclusion.

4. Most comments that addressed this issue supported FDA's tentative determination that the terms "made" and "formed" do not require further elaboration. Comments stated that current implementation of section 403(d) of the act is adequate to prevent containers that are made or formed as to be misleading, and that no significant unaddressed problems exist in the marketplace with respect to these provisions.

On the other hand, two comments stated that FDA had not gone far enough in its proposed regulation. These comments maintained that the agency should address the "made" or "formed" as to be misleading provisions of section 403(d) of the act. In support of their position, the comments cited examples of misleading packaging practices, e.g., packages made with false bottoms, similar to the examples that FDA provided in the misleading container proposal (58 FR 2957) to explain the meaning of the "made" and "formed"

provisions in section 403(d) of the act. These comments stated that such practices would mislead consumers and, therefore, should be addressed by regulations implementing section 403(d) of the act. These comments did not provide information that such products are currently being marketed.

After careful consideration of the comments, FDA finds that the comments have not provided any basis on which to conclude that there are significant unaddressed problems with respect to containers that are made or formed so as to be misleading. Of the States that have adopted regulations prohibiting misleading containers, most have adopted the "made" and "formed" language of section 403(d) of the act without elaboration. Based on these factors, FDA finds that it is not necessary to elaborate by regulation on when a container is so made or formed as to be misleading to fully implement section 403(d) of the act. As discussed in the misleading container proposal (58 FR 2957 at 2960), the agency believes that the misleading packaging practices cited by the comments, such as the use of side walls and false bottoms whose only purpose is to create empty space (i.e., space devoid of product), are clearly misleading, and that therefore, no elaboration of section 403(d) of the act is necessary to establish that such practices constitute misbranding under the act.

Thus, FDA concludes that the statement in § 100.100 that a food is misbranded if "its container is so made, formed, or filled as to be misleading" adequately addresses misbranding that results from the way in which a container is made or formed, and that this approach is consistent with that of the States that have chosen to adopt regulations of this type.

Accordingly, FDA is incorporating the language of section 403(d) of the act in the first paragraph of new § 100.100, as proposed but concludes that no elaboration is necessary.

5. One comment stated that, because FDA has not elaborated on the "made" or "formed" provisions of section 403(d) of the act, the heading for proposed § 100.100 should read "Misleading fill" rather than "Misleading containers."

FDA disagrees. Section 403(d) of the act deals with misleading containers. As discussed in the proposal (58 FR 2957), the misleading container provisions of section 403(d) of the act may be triggered by misleading packaging practices (i.e., containers that are made or formed as to be misleading) or by misleading fill. Although FDA has chosen not to elaborate on the "made" or "formed" aspects of section 403(d) of

the act, it is incorporating these provisions of section 403(d) in new § 100.100 in their entirety. Therefore, FDA finds that the heading "Misleading containers" is appropriate and is so designating new § 100.100.

D. Misleading Slack-fill

6. Two comments stated that a food is misbranded if its container includes misleading slack-fill, regardless of whether the slack-fill is functional or nonfunctional. One comment provided examples of slack-fill that, in its view, would be misleading even though the comment believed that the exceptions set out in proposed § 100.100 would exclude such examples from the proposed definition of nonfunctional or misleading fill. For example, the comment described two opaque coffee-cups containing candy, wrapped in cellophane, and sold as gift items. One cup was filled to capacity while the other contained filler in the nonvisible portion of the cup and a smaller amount of candy at the top. The comment stated that the two cups appeared to contain the same amount of candy, notwithstanding accurate net weight statements. The comment assumed that both products would be lawful under proposed § 100.100(a)(5) which the comment interpreted as exempting all gift products from the definition of nonfunctional slack-fill as misleading fill. The comment suggested that FDA eliminate any possible ambiguity by modifying proposed § 100.100(a) to read: "(a) A container shall be considered to be filled as to be misleading if it contains nonfunctional slack-fill or if it contains slack-fill which facilitates the perpetration of deception or fraud."

A second comment suggested that FDA add a new paragraph (b) to proposed § 100.100 stating that even when a package meets the criteria for the exceptions in proposed § 100.100(a)(1) through (a)(5), the package may still be misleading. This comment stated that such a new paragraph should read as follows: "(b) Notwithstanding compliance with subsection (a)(1) through (a)(5), a food shall be misbranded within the meaning of section 403(d) of the Federal Food, Drug, and Cosmetic Act if it is packaged in such a way as to be deceptive or misleading."

FDA believes that the comments misinterpreted the intent of the exceptions to the definition of nonfunctional slack-fill set out in § 100.100(a). In the misleading container proposal (58 FR 2957 at 2961), FDA proposed "nonfunctional slack-fill" as the empty space in a package that is filled

to substantially less than its capacity for reasons other than to accomplish a specific functional effect. FDA set out in proposed § 100.100(a)(1) through (a)(5) types of products or practices that typically result in slack-fill within a container but as a part of which, the agency tentatively concluded, the slack-fill performs a specific functional effect.

FDA advises that the exceptions to the definition of "nonfunctional slack-fill" in § 100.100(a) apply to that portion of the slack-fill within a container that is necessary for, or results from, a specific function or practice, e.g., the need to protect a product. Slack-fill in excess of that necessary to accomplish a particular function is nonfunctional slack-fill. Thus, the exceptions in § 100.100(a) provide only for that amount of slack-fill that is necessary to accomplish a specific function. FDA advises that these exceptions do not exempt broad categories of food, such as gift products and convenience foods, from the requirements of section 403(d) of the act. For example, § 100.100(a)(2) recognizes that some slack-fill may be necessary to accommodate requirements of the machines used to enclose a product in its container and is therefore functional slack-fill. However, § 100.100(a)(2) does not exempt all levels of slack-fill in all mechanically packaged products from the definition of nonfunctional slack-fill.

Consequently, in the case of gift products such as those described by the first comment (i.e., coffee cups filled with candy), reasonable amounts of slack-fill that result from differences in the volume of the container (whose size is also related to its use after the food is consumed) and the amount of food contained therein is a function of the nature of the gift product and the continued utility of the container. Slack-fill in excess of that which is dictated by reasonable differences in the volume of a gift container and the amount of food contained therein is nonfunctional slack-fill.

Space within a container that is devoid of product is slack-fill, regardless of whether it contains air or "filler." FDA finds that slack-fill whose only function is to mislead consumers is nonfunctional slack-fill. FDA also finds that deceptive methods of packaging whereby that portion of the contents displayed gives the consumer an erroneous impression as to the quantity of product in a container, whether such deception is accomplished through misleading fill, misleading packaging, or both, is misbranding.

FDA finds that the above suggestions are redundant with respect to the provisions of § 100.100 that already

state that a food is misbranded if its container is so made, formed, or filled as to be misleading. Thus, the six categories of functional slack-fill listed in § 100.100(a) do not provide a "safe haven" from deceptive packaging practices: packages whose slack-fill is functional but that are otherwise made, formed, or filled in a manner that is misleading still violate section 403(d) of the act.

The agency notes that in cases such as *United States v. 174 Cases * * * Delson Thin Mints*, 195 F. Supp. 326 (D.N.J. 1961), *aff'd* 302 F.2d 724 (3d. Cir. 1962), courts have ruled that the phrase "misleading fill" is too vague to permit direct enforcement. FDA advises that the intent of § 100.100(a) is to ensure the adequate implementation of section 403(d) of the act by providing a more concrete, enforceable definition for the phrase "misleading fill." Thus, FDA finds that establishing a two-pronged test where one of the tests is whether a container is filled so as to be misleading, as suggested by the comment, does nothing to elaborate on the meaning of "misleading fill" or "misleading container" and is therefore contrary to the intent of this rulemaking.

FDA also disagrees with the suggestion that functional slack-fill might be misleading slack-fill. In *United States v. 174 Cases * * * Delson Thin Mints*, the court ruled that "the efficacy of the packaging, both from the standpoint of protecting the product and from the standpoint of economy of manufacture outweighs its deceptive quality," provided that no less deceptive alternative is available. FDA advises that the exceptions to the definition of "nonfunctional slack-fill" in new § 100.100(a) are meant to elaborate on the circumstances in which slack-fill within a package is functional slack-fill as opposed to misleading fill. To the extent that such slack-fill, or the practice that results in such slack-fill, performs a necessary function, it would not constitute nonfunctional slack-fill and thus would not be misleading within the meaning of the term in section 403(d) of the act.

FDA finds that adding a new paragraph (b), as suggested, would fail to recognize that slack-fill is justified when it performs a necessary function in a packaged food product. FDA also finds that to be consistent with the findings in cases such as *United States v. 174 Cases * * * Delson Thin Mints*, functional slack-fill as provided for in § 100.100(a)(1) through (a)(6) is not misleading fill. Therefore, FDA must deny the request.

7. One comment suggested that, if FDA does not include a provision

prohibiting misleading fill as requested by the preceding comments (i.e., as a two-pronged test), the agency should amend the language in § 100.100(a) to clarify that these exceptions apply only to necessary or unavoidable slack-fill. For example, the comment suggested that proposed § 100.100(a)(3), which provides for normal product settling during shipping and handling, be changed to read "unavoidable product settling * * *."

FDA agrees. FDA notes that the "necessary or unavoidable" aspect of functional slack-fill is expressed in several exceptions in § 100.100 by phrases such as "the requirements of the machines * * *" (§ 100.100(a)(2)) and "the need for the package to perform a specific function * * *" (§ 100.100(a)(4)). As stated above, FDA finds that the exceptions to the definition of nonfunctional slack-fill in § 100.100(a) apply to that portion of the slack-fill within a container that is necessary for, or results from, a specific function or practice, e.g., the need to protect a product. The agency also finds that slack-fill in excess of that necessary to accomplish a particular function is nonfunctional slack-fill.

FDA notes that many factors influence the amount of settling in a product. The physical characteristics of the product, e.g., particle size and shape, product density, and product fragility, will dictate how densely a product can be packed without an increased incidence of product breakage. Further, some packaging equipment shakes the container to encourage product settling during the filling operation, thereby achieving a greater level of fill within the container and reducing subsequent product settling. FDA finds that, to the extent that the physical characteristics of the product and the limitations of the filling machine contribute to product settling during shipping and handling, such slack-fill is functional slack-fill. On the other hand, FDA finds that adjusting line speed and filling equipment such that product is more loosely packed than necessary, i.e., to temporarily achieve what appears to be a full container, would not constitute functional slack-fill under § 100.100(a)(3).

Accordingly, FDA is amending § 100.100(a)(3) to specify that slack-fill resulting from product settling during shipping is functional slack-fill when such slack-fill is unavoidable.

E. Nonmisleading Nonfunctional Slack-fill

In the preamble to the misleading container proposal, FDA tentatively concluded (58 FR 2957 at 2961) that

slack-fill in excess of that required to perform a function in a food is nonfunctional and, therefore, misleading. FDA also invited comment on whether it makes a difference if a product is packaged in a container that allows consumers to fully view the contents of the container (58 FR 2957 at 2962).

8. Ten comments objected to the provisions of proposed § 100.100 that equate nonfunctional slack-fill with misleading fill. Several comments stated that neither the FPLA nor section 403(d) of the act says "nonfunctional slack-fill is misleading," yet proposed § 100.100 concludes that nonfunctional slack-fill constitutes misbranding.

Several comments stated that FDA failed to specify that product that fails to meet the criteria in proposed § 100.100 is not misbranded unless such failure results in deception. One comment stated that, absent a finding of consumer deception by FDA, nonfunctional slack-fill should not render a product misbranded. These comments maintained that products packaged in containers that allow consumers to fully view the contents of the package should be exempt from the definition of nonfunctional slack-fill as misleading fill. One comment stated that fill of container could not be misleading when product is packaged in "clear or fairly clear" packages.

One comment stated that § 100.100 should provide for adequate disclosure of slack-fill in packages. The comment acknowledged, however, that label disclosure of slack-fill will not dispel such visual misrepresentations as caused by egregiously oversized packages. Another comment stated that if consumers can be informed of any level of slack-fill within the package, through label statements, pictorials, or other devices, they cannot be deceived as to the fill of the container. Several comments cited the protection against deception provided for by net weight statements.

Finally, one comment stated that level of fill is irrelevant in a single-serve package so long as the package contains sufficient product to accomplish its intended effect, e.g., enough sweetener to sweeten a cup of coffee. Thus, the comment maintained, it would not be misleading for slack-fill to exist in any single-serve package that clearly indicates the content's volume.

FDA disagrees with the comments that stated the agency has no basis for equating nonfunctional slack-fill with misleading fill. From the beginning of deliberations to revise the Food and Drugs Act in 1933, a major goal was to protect consumers from packages that

are made or filled so as to be misleading. Senator Copeland (78 Congressional Record (May 16, 1934) as quoted in Dunn, *Federal Food, Drug, and Cosmetic Act* 161) stated "Another dishonest practice that escapes the present law, but can be stopped under S. 2800 [section 403(d)] is that of slack filling containers of food * * *." Congress determined (S. Rept. 361, 74th Cong., 1st sess. 9 (1935)) that packages that are only partly filled (containing slack-fill) create a false impression as to the quantity of food they contain. Thus, throughout the legislative history of the enactment of the misbranding provisions in section 403(d) of the act, slack-fill has been equated with misleading fill.

Recognizing that factors such as product shrinkage after shipping may result in slack-fill within a package, Congress stated that the provision in section 403(d) of the act "is not intended to authorize action against packages that are filled as full as practicable in good manufacturing practice." (S. Rept. 361, supra at 9.) This statement, although allowing for the presence of some amount of unavoidable slack-fill, reinforces the concept that, from the standpoint of fill, nonmisleading containers are those that are filled as full as practicable.

In section 2 of the FPLA, Congress states that "Informed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information as to the quantity of contents and should facilitate value comparison." Section 5(c) of the FPLA provides for the promulgation of regulations, including regulations prohibiting nonfunctional slack-fill, to facilitate value comparisons and to prevent consumer deception. Thus, the FPLA equates nonfunctional slack-fill with misleading fill. Further, California adopted the language of the FPLA for nonfunctional slack-fill as a basis for prohibiting misleading fill. Finally, the IOM suggested that FDA also consider using the FPLA definition of nonfunctional slack-fill as a basis for regulations to ensure adequate implementation of section 403(d) of the act. FDA concludes that there is adequate basis for using a definition of nonfunctional slack-fill as a means to implement the intent of section 403(d) of the act.

FDA finds that language similar to that used in the FPLA will ensure adequate implementation of the misleading container provisions of section 403(d) of the act and is consistent with the intent of both the

FPLA and section 403(d). Therefore, FDA is establishing new § 100.100 which, among other things, defines the circumstances in which the slack-fill within a package is nonfunctional and, therefore, misleading.

FDA also advises that the standard in section 403(d) of the act is whether a container is misleading as opposed to deceptive or fraudulent. According to Webster's II New Riverside University Dictionary, "fraud" is "A deliberate deception practiced so as to secure unfair or unlawful gain." Webster's defines "deceptive" as "intended or tending to deceive," whereas "misleading" is defined as "tending to mislead." FDA advises that the term "misleading" does not require any clear implication regarding intent. Thus, it is not incumbent upon the agency to prove deception in order to deem a food to be misbranded under section 403(d) of the act. Rather, FDA is defining misleading fill as nonfunctional slack-fill. Thus, the appropriate test is whether or not the empty space within a package performs a specific function in relation to the product or its packaging. FDA finds that it is incumbent on manufacturers, knowing the physical characteristics of their products and the capabilities of their packaging equipment, to ensure that any slack-fill in their packages is there to perform one or more valid functions. Slack-fill whose only function is to make the product container larger, and thus to deceive the consumer as to the quantity of food in the container, is nonfunctional slack-fill and, therefore, misleading.

With respect to transparent containers, FDA notes that section 403(d) of the act is intended to prohibit partially filled packages that give a false impression as to the quantity of food they contain. FDA is not aware of there ever having been any action against a product that was allegedly filled so as to be misleading that was packaged in a container that allowed consumers to fully view its contents. Nor can FDA conceive of any situation related to fill of container where consumers would be misled as to the quantity of contents in such a container. Therefore, FDA is modifying § 100.100(a) to specify that a container that does not allow consumers to fully view its contents shall be considered to be filled as to be misleading if it contains nonfunctional slack-fill. This action acknowledges that misleading fill has not been an issue when consumers can clearly see the level of fill in a container.

FDA advises that the exception for containers that allow consumers to fully view the contents of the container applies to packages that are constructed

in such a way and made from such materials that consumers can fully see the amount of product they are purchasing and, consequently, could not be misled as to the level of fill in the container. This exception would apply to containers made of transparent material such as a glass jar or a clear poly bag. It does not refer to containers made of translucent material that must be held up to the light, nor does it apply to transparent containers bearing labeling or graphics such that the consumer's clear view of the contents is obscured.

FDA also advises that the above exception applies only to considerations of fill. FDA believes that, in a transparent container, level of fill would not, by itself, mislead consumers as to the quantity of product. However, it is conceivable that transparent containers could be made, shaped, or formed in such a way as to mislead consumers as to the quantity or quality of contents. Consequently, FDA finds that the prohibition against containers that are made or formed as to be misleading applies to both transparent and nontransparent containers.

FDA advises that the entire container does not need to be transparent to allow consumers to fully view its contents, i.e., a transparent lid may be sufficient depending on the conformation of the package. On the other hand, FDA finds that devices, such as a window at the bottom of a package, that require consumers to manipulate the package, e.g., turning it upside down and shaking it to redistribute the contents, do not allow consumers to fully view the contents of a container. FDA finds that such devices do not adequately ensure that consumers will not be misled as to the amount of product in a package. Therefore, such foods remain subject to the requirements in § 100.100(a) that slack-fill in the container be functional slack-fill. Further, FDA advises that displaying a portion of the contents in such a way as to give consumers an erroneous impression of the quantity of contents in a package, whether through misleading packaging or through misleading filling practices, constitutes misbranding.

FDA disagrees with the comments that stated that net weight statements protect against misleading fill. FDA finds that the presence of an accurate net weight statement does not eliminate the misbranding that occurs when a container is made, formed, or filled so as to be misleading.

Section 403(e) of the act requires packaged food to bear a label containing an accurate statement of the quantity of contents. This requirement is separate

and in addition to section 403(d) of the act. To rule that an accurate net weight statement protects against misleading fill would render the prohibition against misleading fill in section 403(d) of the act redundant. In fact, Congress stated (S. Rept. No. 493, 73d Cong., 2d sess. 9 (1934)) in arriving at section 403(d) of the act that that section is "intended to reach deceptive methods of filling * * * where the package is only partly filled and, despite the declaration of quantity of contents on the label, creates the impression that it contains more food than it does." Thus, Congress clearly intended that failure to comply with either section would render a food to be misbranded.

In the misleading container proposal (58 FR 2957 at 2959), FDA noted that some manufacturers employ label statements such as "Contents may settle during shipping" or "Contents sold by weight, not volume" to inform consumers that a package will probably appear to be less than full. Statements such as "A certain amount of air is packaged in each bag to act as a cushion against breakage" alert consumers as to the presence of slack-fill and provide information on the function of the slack-fill. FDA believes that such label statements may reduce consumer dissatisfaction with functional slack-fill and, therefore, encourages their use. However, FDA finds that label statements cannot correct nonfunctional or misleading fill.

FDA also disagrees with the comment that stated that slack-fill would not be misleading in any single-serve package that indicates the volume of the contents. FDA finds there is no reason to treat single-serve packages differently from packages that contain multiple servings with respect to prohibiting nonfunctional slack-fill. To the extent that slack-fill exists in some single-serve packages (e.g., packages of table salt or coffee creamer) because the manufacturer is unable to further reduce the size of the package, such slack-fill is a function of a minimum package size requirement, as set out in § 100.100(a)(6). In addition, manufacturers may package products, such as high intensity sweeteners, in premeasured packets for the convenience of consumers. Thus, a portion of the slack-fill in such packages may result from the need for the package to perform a specific function, e.g., to provide convenience, and would therefore be functional slack-fill within the provisions of § 100.100(a)(4). However, to the extent that slack-fill in a single-serve package serves no purpose other than to mask the amount

of product present, it is misleading. Therefore, FDA must deny the request.

F. Related Products—Single Packaging Machine

9. Several comments stated that it is common practice to use one package size and a single line or filling machine to package related products. These comments maintained that any law regulating fill-of-container must take into account the benefits of common packaging, at least for related products. One comment described a single line operation used to package a variety of frozen vegetables in the same-size poly bag. The comment stated that, although it believes the use of the same-size bags is appropriate, differences in the size and shape of various vegetables, such as peas and broccoli florets, will result in different levels of slack-fill within each package. The comment suggested that FDA specify that related products may be packaged on a single line. Another comment maintained that FDA should recognize as functional slack-fill that slack-fill that results from the practice of packaging oddly shaped products, especially seasonal items such as a chocolate Santa or an Easter bunny, in a common package.

As stated in the misleading container proposal (58 FR 2957 at 2961), this regulation is not intended to require manufacturers who are operating under current good manufacturing practice to change the physical characteristics of a food, nor is it intended to require manufacturers to purchase additional or more sophisticated packaging equipment. FDA finds that the exception from the definition of "nonfunctional slack-fill" for slack-fill resulting from the requirements of the filling machine adequately covers the use of a single filling machine to package related products when such use is appropriate, without further exemptions. For example, even though the above mentioned chocolate Easter bunny and chocolate Santa may be of approximately similar height and width, their shapes are very different.

Therefore, packaging both products in the same container would result in different levels of slack-fill for each product. However, the slack-fill in each box may still be functional slack-fill if it is justifiable based on the conformation of the specific products. On the other hand, using the same-size package for an Easter bunny that is 12 inches (in) tall by 6 in wide and for a chocolate ornament that has a 6-in diameter would not be appropriate.

FDA advises that the amount of slack-fill in a package is the result of both the size of the container and the level of fill

therein. FDA notes that manufacturers wishing to market related products in a single, uniform container may vary the amount of product in each container to compensate for difference in the physical characteristics of a particular product. For example, a spice manufacturer may fill one jar with 10 grams (g) of a leafy herb, such as parsley or basil. However, in the case of a denser spice, such as ground cumin, it would require approximately 50 g of product to fill the same size jar as full as practicable. The price of each item would then be adjusted to reflect both the relative value and the amount of the product in each container.

Equipment manufacturers often design filling equipment to accommodate different packaging needs, e.g., cups of different heights with the same diameter (lid size) or the ability to heat seal packages of varying length from a continuous sleeve of packaging material. Further, some equipment is designed so that a simple adjustment can be made, such as changing the size of the spacers between the knives used to cut candy bars to a given length, that changes the size of the product or the fill of container. Therefore, depending on the versatility of the machines used to manufacture a product and to fill a container, owning a single filling machine does not necessarily limit a manufacturer to a single package size or a single level of fill.

G. Small Package Exception

FDA invited comment on the appropriateness of establishing an exemption from the definition of nonfunctional slack-fill for packages containing slack-fill that results from an inability to further reduce the size of the package. The agency noted that some food products (e.g., saffron and saccharin) are frequently sold in very small quantities for various reasons, including limited shelf-life, high cost per unit volume, or the need to use only a small amount of the product at any one time.

10. Several comments stated that small packages often contain slack-fill that results from an inability to further reduce the size of the package. Comments maintained that such slack-fill is a function of a minimum package size requirement. Comments suggested that proposed § 100.100(a) be modified to specify that slack-fill resulting from an inability to further reduce the size of the package is not nonfunctional slack-fill.

One comment argued that, in addition to FDA's basic food labeling requirements, packages must bear a UPC code (Universal Product Code) and, in

many cases, directions for preparation or use of the product. The comment urged FDA to find that products packaged in the minimum-size package necessary to accommodate all required labeling information in a readable format are not misleadingly filled.

Another comment stated that a minimum package size may be necessary to accommodate package inserts such as dosing devices (e.g., measuring scoops), coupons, and other premiums. Several comments stated that a minimum package size is necessary to facilitate handling and to discourage pilfering. Comments maintained that reducing package size beyond a certain point would be impracticable and could result in retailers delisting products that are packaged in very small containers.

FDA agrees that reducing package size beyond a certain point may cause problems. However, because slack-fill is the difference between the volume of a container and the amount of food contained therein, manufacturers can control the amount of slack-fill through choice of container size or through the level of fill within the container. At the same time, FDA realizes that some products, such as products that are used in small amounts and products with limited shelf-life or high unit cost, must be sold in small quantities. For example, products such as saffron are sold in such small quantities (e.g., 2 g or less) that a package with no slack-fill could be easily lost or stolen. Further, increasing levels of fill may not be an option because of the high unit cost.

FDA also notes that additional factors, including marketing data and handling and distribution requirements have an effect on what would constitute the minimum package size for a particular product. Some products such as breath mints and bakers yeast may be packaged in containers with very small volumes (i.e., less than 2 cubic in). Such products are often sold from a bin attached to a shelf or rack in a specific location within the store. Thus, even though these products are sold in small quantities, manufacturers and retailers have devised systems to facilitate handling of the products, thereby allowing the product to be packaged in a container whose size accurately reflects the amount of product therein. Further, some small packages are attached to a larger card such that consumers can clearly see the size of the container, while the card provides additional surface area to bear labeling, to facilitate handling, or to discourage pilfering.

Usage patterns may also influence the level of fill in a package that is already relatively small. For example, market

data may show that the appropriate level of fill for products that are expected to be prepared and consumed at a single sitting would be that amount necessary to serve a typical family of four. In the case of a gelatin mix sweetened with a high intensity sweetener, this amount would be no more than 0.5 ounce (oz) of product.

FDA finds that, to the extent that such foods must be sold in small quantities, and be packaged in a container of some minimum size to accommodate required food labeling (excluding any vignettes or other nonmandatory designs or label information), discourage pilfering, facilitate handling, or accommodate tamper-resistant devices, the resulting slack-fill is functional slack-fill. Therefore, FDA is adding new paragraph (a)(6) to § 100.100, which states that the empty space in a package that results from an inability to further reduce the size of the package is not nonfunctional slack-fill. FDA advises, however, that manufacturers relying on this exception should be prepared to demonstrate that the level of fill is appropriate for the particular product, and that package size cannot be further reduced.

H. Slack-fill Resulting From Product Reformulation

In the misleading container proposal (58 FR 2957 at 2962), FDA noted that product reformulation may change the density, weight, or volume of a product, sometimes drastically. For example, the agency described a package containing approximately 3 oz (85 g) of gelatin mix sweetened with sugar. The same product sweetened with a high intensity sweetener may weigh only 0.5 oz (14 g). If the manufacturer uses the same package for both products, the package containing gelatin sweetened with the high intensity sweetener will contain a significantly greater amount of slack-fill. The agency noted that the increased slack-fill in the package containing 0.5 oz of product exceeds the amount of slack-fill that is required to perform such necessary functions as protecting the product and ensuring proper package closure in the package that contains 3 oz of product. The agency tentatively concluded (58 FR 2957 at 2962) that, absent a functional effect, the portion of slack-fill within a container resulting from product reformulation (e.g., removal of a macronutrient such as sucrose) that reduces the volume of product in that container constitutes nonfunctional (misleading) slack-fill. The agency invited comment on this tentative conclusion and on the criteria that could be used to distinguish between functional (justifiable) and

nonfunctional (misleading) slack-fill in a case such as this.

11. Five comments strongly disagreed with the agency's tentative conclusion that an artificially sweetened version of a food (0.5-oz net weight) would be misleading if it were packaged in the same-size container as the conventionally sweetened product (3.0-oz net weight). One comment maintained that, in the 9 years this type of product has been on the market, consumers have learned that removing a bulky constituent, such as sucrose, may reduce the total volume of a food. Comments further maintained that consumers associate package size with the amount of finished product, not the amount of mix in a package. Several comments argued that if the package containing a food formulated with a high intensity sweetener were made smaller, consumers would assume that the amount of finished product from the smaller package would be less. Thus, comments argued, this is a case where conforming package size to the physical amount of product would be misleading. One comment maintained that the high volume of repeat sales for such products, e.g., dessert mixes sweetened with a high intensity sweetener, is further evidence of the lack of consumer deception.

Similarly, a comment from a food manufacturer stated that it produces different versions of a hot cocoa mix in single-service envelopes packaged in point-of-sale cartons. The products vary in formulation, sweeteners, product density, and net weight. Each version of the food is packaged in the same-size envelope and similar box and produces the same amount of finished product. The comment maintained that of the 70,000 letters and inquiries it received from consumers in the last year, only 2 questioned why the sugar-free diet hot cocoa mix was packaged in the same-size container as the regular hot cocoa mix.

On the other hand, one comment gave the example of a sugar-free diet product where a portion of the increase in slack-fill resulting from product reformulation would, in its view, constitute misleading fill. The comment included copies of two containers, one for a sugar-free product and the other for a diet version of the sugar-free food. The comment maintained that consumers expect the weight and volume of a sugar-free food to be less than the conventional food because of the removal of the bulky sweetener. However, according to the comment, the diet sugar-free version of the food achieves its lower caloric value largely by reducing the level of a major

nutritive ingredient. According to the comment, the volume of the resulting diet product is one-third less than that of the regular sugar-free food. The comment suggested that FDA specify that slack-fill resulting from the removal of an essential nutritive ingredient constitutes misleading fill.

FDA notes that reformulated products and substitute foods cover a very broad range of products. Product reformulations are not limited to the removal of bulky constituents such as sucrose but include product reformulations that result in less dramatic changes in product volume. For example, a manufacturer of a dried pasta salad mix who uses a tube-shaped macaroni product may also market a second type of pasta salad mix using a spiral shaped pasta product. Because the pasta component of each mix has a different shape, each mix would occupy a different volume within the container while still providing the same amount of finished product (e.g., six 140-g servings). The degree to which product reformulation changes the amount of slack-fill in a container depends on the degree to which the shape or density of the new ingredient differs from that of the original ingredient and on the effect of the reformulation on the volume of the food.

Consumers develop expectations as to the amount of product they are purchasing based, at least in part, on the size of the container. The congressional report that accompanied the FPLA stated: "Packages have replaced the salesman. Therefore, it is urgently required that the information set forth on these packages be sufficiently adequate to apprise the consumer of their contents and to enable the purchaser to make value comparisons among comparable products" (H.R. 2076, 89th Cong., 2d sess., p. 7 (September 23, 1966)). Thus, packaging becomes the "final salesman" between the manufacturer and the consumer, communicating information about the quantity and quality of product in a container. Further, Congress stated (S. Rept. 361, supra at 9) that "Packages only partly filled create a false impression as to the quantity of food which they contain despite the declaration of quantity of contents on the label."

In cases such as *United States v. 174 Cases *** Delson Thin Mints* and *United States v. 116 Boxes *** Arden Assorted Candy Drops*, 80 F. Supp. 911, 913, (D. Mass., 1948), the courts have ruled that the standard against which misleading fill should be tested is whether the container would be likely to mislead the ordinary purchaser as to

the quantity of its contents. In other words, would the average consumer expect to find more product in a package than that which is contained therein? FDA agrees that many consumers who have become familiar with substitute foods, such as a dry dessert mix sweetened with a high intensity sweetener, understand that removing the bulky sweetener may result in a smaller volume of mix, while the amount of finished product remains the same. However, consumers who are not familiar with a particular substitute food may be misled as to the amount of product that they are purchasing if the amount of product changes, and the size of the container remains the same. Such confusion is evidenced by the comment that acknowledged receiving two letters questioning why a small amount of a substitute food was packaged in the same-size container as that used to hold a larger quantity of the regular product. FDA also notes that, although consumers may become used to the presence of nonfunctional slack-fill in a particular product or product line, the recurrence of slack-fill over an extended period of time does not legitimize such slack-fill if it is nonfunctional.

Further, FDA disagrees with the comments that stated that packaging a substitute or reformulated food in a smaller container than the regular product would be potentially misleading about the amount of finished product that the substitute or reformulated food would produce, i.e., that consumers would assume that the smaller container provides a smaller amount of finished product. FDA notes that, because of consumer interest in environmental issues such as minimal packaging and recycling and because of economic incentives to reduce packaging, shipping, and storage costs, many products are being marketed in forms such as concentrates and refills. The fact that the smaller package provides as much product as a larger package can be readily communicated to the consumer. Just as label statements such as "packed by weight not volume" may be used to explain functional slack-fill, label statements such as "Special blend, this 39 ounce can provides at least 36 more cups of coffee compared to a 3 pound (48 ounce) can of regular coffee" may be used to explain that a small package provides as much or more product than a larger package. FDA advises, however, that label statements do not dispel the misleading aspect of nonfunctional slack-fill.

FDA finds that product reformulation does not, by itself, justify slack-fill in excess of that which is functional in the regular or original product. On the other

hand, slack-fill in different versions of related products may be functional slack-fill under § 100.100(a)(2) (requirements of filling machines), provided that the manufacturer is making appropriate use of available packaging materials and filling equipment. Furthermore, FDA recognizes that reducing package size below a certain minimum may not be possible and has provided for slack-fill resulting from an inability to further reduce the size of a package in § 100.100(a)(6). Thus, in the case of products such as gelatin sweetened with a high intensity sweetener, where a product is sold in small amounts, slack-fill may be a function of a minimum package size requirement.

FDA agrees with the comment that stated that removal of an essential nutritive ingredient from a food is potentially misleading. As stated above, product reformulation does not, by itself, justify slack-fill in excess of that which is functional in the regular or original product. Thus, it is incumbent on the manufacturer of a substitute food to demonstrate that the slack-fill in their packages does not exceed that which is necessary to perform a function for the food.

FDA also advises that foods that purport to be useful in maintaining or reducing caloric intake or body weight must conform to the requirements of § 105.66 (21 CFR 105.66), including the requirement that they not be nutritionally inferior to the food for which they substitute. A substitute food that is nutritionally inferior to the food for which it substitutes must be labeled "imitation". Absent this labeling, the food is misbranded under section 403(c) of the act. However, section 403(c) is separate and apart from the misleading container provisions in section 403(d) of the act.

I. Immediate Container

12. One comment stated that slack-fill applies only to the immediate container in which a food is packaged, and that it never refers to the amount of unfilled space between the immediate container and external packaging. The comment defined "immediate container" as that portion of the packaging that is in immediate contact with the product. The comment suggested, for example, that in the case of a dry dessert mix formulated with a high intensity sweetener and a conventionally sweetened dessert mix, both products could be packaged in the same-size box because the only place where slack-fill needs to be considered is within the package liner that immediately contains the dry mix. Therefore, according to the

comment, manufacturers could avoid excess slack-fill by reducing the air space in the package liner containing the dry mix made with a high intensity sweetener. The comment also stated that, to the extent that there is any issue with respect to the use of the same-size outer box for both regular and sugar-free products, the issue is one of potentially deceptive packaging and not slack-fill.

FDA disagrees with the comment's interpretation of "immediate container." Section 201(l) of the act (21 U.S.C. 321(l)) specifically states that the phrase "immediate container" does not include package liners. Furthermore, section 10(b) of the FPLA (15 U.S.C. 1459(b)) defines "package" as " * * * any container or wrapping in which any consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers * * *." Thus, the box that the consumer sees when purchasing the dessert mix, not the bag within the box, is the immediate container. The amount of slack-fill in the dessert mix package would be based on the volume of the box. The term "package", as defined in the FPLA, does not include shipping containers or wrapping used solely for transport or such containers or wrappings that bear no printed matter pertaining to any particular commodity.

FDA also advises that deceptive packaging refers to containers that are made or formed so as to be misleading, such as containers made with false bottoms. Therefore, the issue involved in the example provided by the comment, i.e., two products that differ in volume but produce similar amounts of finished product, is one of fill, not packaging.

J. Additional Exceptions to the Definition of "Nonfunctional Slack-fill"

Many comments, although generally in favor of proposed § 100.100, requested clarification of various provisions of the proposal or suggested additional exceptions to the proposed definition of nonfunctional slack-fill. Specific comments were as follows.

Machine Requirements

13. Several comments stated that FDA has not formally recognized all the requirements of the machines used for enclosing the contents of a package. One comment stated that other machines, such as equipment used to fill to headspace above a product with nitrogen to protect the product from oxidation, have fill requirements. Comments urged FDA to recognize that slack-fill that results from the requirements of machines used to enclose the contents in a package is not

limited to filling machines but may include other machines used to process or package the product.

FDA agrees that packaging a product may involve a series of unit operations, such as: (1) Filling product in a container, (2) flushing headspace with nitrogen, and (3) sealing the container. Each unit operation may require use of a single, specialized piece of equipment. FDA advises that the statement in § 100.100(a)(2) that recognizes that slack-fill that results from the requirements of "the machines used for enclosing the contents in such package" is not nonfunctional covers not only the requirements of the filling machine itself but of all equipment involved when product and package come together. FDA finds that, to the extent that slack-fill is necessary for the efficient functioning of the machines used to enclose the contents in a package, such slack-fill is functional slack-fill.

14. Two comments stated that, in some instances, vending machines only accommodate a standard size package. Thus, products sold in vending machines may have some empty space related to the constraints of the vending machine and the value of the product relative to the expected price range for products sold in a vending machine. The comments requested that slack-fill in a vending machine package be recognized as a function of "the requirements of the machines used for enclosing the contents in such package" as set out in § 100.100(a)(2).

FDA disagrees. The provisions in § 100.100(a)(2) provide for slack-fill resulting from the requirements of the machines used to enclose a product within a container. FDA notes that this exception is specific to those machines involved in bringing together a product and its package. The exception does not extend to all machines used in the manufacture, distribution, and sale of a food.

FDA advises that many vending machines are able to accommodate a wide variety of package sizes and shapes. Further, many vending machines are able to dispense different products at different prices, such as a package of gum, a candy bar, or a bag of potato chips, from a single machine. The comments did not provide any evidence that the requirements of vending machines would result in the presence of functional slack-fill in a significant number of products. Furthermore, when consumers contemplate purchasing a product from a vending machine, value comparisons based on visual assessment of the product, including the size of the

package, become even more important compared to other purchasing situations. Thus, after careful consideration of the comments, FDA finds that there is no basis to exempt the slack-fill in containers that are sold through vending machines from the definition of "nonfunctional slack-fill" in § 100.100(a).

Gift Products

15. Several comments stated that the exception to the definition of nonfunctional slack-fill in proposed § 100.100(a)(3) should not be limited to gift products. Comments provided examples of packaging that is intended for reuse by consumers but that is not necessarily sold as part of a gift item. Examples included canisters designed as coin banks or for other storage uses; holiday, commemorative, or collectors items; and jars that can be used as glasses. Comments maintained that these items are often meant as promotional packs rather than gift items. One comment suggested that FDA exempt gift items or "products packaged in other reusable containers." In order to qualify for such an exemption, the comment suggested the following criteria: (1) That the quality of the package greatly exceed that which is necessary to merely contain the product, and (2) that the package play a primary role in the presentation of the food. The comment maintained that cheap packages such as those made of "flimsy cardboard without additional covering" should not be included in this exemption. The comment also stated that the size and conformation of most reusable containers, other than household items, can be easily controlled.

On the other hand, one comment maintained that manufacturers of gift-type products in nonreusable containers, where the container plays a role in the presentation of the food, need the same amount of flexibility as manufacturers of gift products in reusable containers. In support of its argument, the comment described two types of containers, e.g., a rectangular cookie tin and a paperboard box, both having the same volume, design, and label vignettes. The comment maintained that the paperboard box would be as attractive as the tin but would be available to consumers at a lower cost.

This comment suggested the following criteria to distinguish gift products from conventional food items: (1) Seasonal items and items sold for special occasions (e.g., holidays and birthdays) where packages are designed to convey appropriate sentiments, and

(2) the quality of the food component exceeds that of the conventional food, and this superior quality is conveyed by the package (e.g., gourmet items sold in specialty food shops).

The comment also maintained that, because FDA has defined a "gift item" merely as a product that "is in a form intended to be used as a gift" in the new nutrition labeling regulations (58 FR 2159 and 2184, January 6, 1993), the distinction between gift items packaged in reusable versus nonreusable containers in this rulemaking is unnecessary. The comment suggested that FDA amend § 100.100(a)(5) to read "where a product is packaged in a form intended to be used as a gift," thereby eliminating the distinction between reusable and nonreusable containers and focusing on the gift nature of the food.

A few comments stated that slack-fill resulting from packaging practices whose value lies in the aesthetics of presenting the product or in conveying a sentiment should be allowed when "the most significant purpose of the package configuration is something other than to misrepresent the quantity of its contents."

FDA agrees with the comment that stated that the proposed exemption for functional slack-fill in gift products (§ 100.100(a)(5)) should be expanded to include products consisting of a food packaged in a reusable container where the container has value that is both significant in proportion to the value of the product and independent of its function to hold the food. FDA advises that part of the purchase of a food packaged in a reusable container is the continued utility of the container. FDA finds that the interest in the reusable container would exist whether consumers purchase the product as a gift or for their own use. Therefore, slack-fill resulting from reasonable differences in the volume of a reusable container and the amount of food contained therein would be functional slack-fill.

FDA notes that, depending on the nature of the food and the type of container used, manufacturers will have varying degrees of control over the amount of slack-fill in the container. FDA disagrees with the comment that stated that manufacturers using nonreusable containers need the same amount of flexibility as manufacturers of gift-type products packaged in reusable containers. FDA finds that manufacturers packaging product in nonreusable containers have more control over the size and conformation of such containers compared to manufacturers packaging product in

certain household items, such as a coffee mug or a tea pot, whose size and shape is also dependent on its intended use after the food is consumed.

FDA finds that the term "reusable container" describes household items (e.g., baskets and coffee cups) and durable commemorative or promotional packaging (e.g., holiday tins and canisters with nostalgic graphics). FDA agrees with the comment that stated that containers made of flimsy materials should not be included in this exemption. FDA advises that the purpose of § 100.100(a)(5) is to provide a certain degree of flexibility to manufacturers of products packaged in containers, such as reusable household items, that have a function above and beyond that of containing the food. Consequently, FDA is retaining the proposed criterion that such containers be reusable after the food is consumed.

FDA advises that the definition of "gift item" in the January 6, 1993, final rule on nutrition labeling (58 FR 2079 at 2159 and 2184) was concerned with providing consumers with accurate and accessible nutrition information that could be used to plan a healthy diet. Thus, the nature of the container was not germane to that final rule. However, this final rule is concerned with the ability of consumers to make appropriate value comparisons based on their perception of the quality and quantity of food in a container. FDA advises that, in this context, any factors that influence the way in which a container is made, formed, or filled are important considerations. FDA finds that some reusable containers are available in a limited range of sizes, and that using such containers to package product may result in slack-fill that is, in part, a function of the size of the container relative to its continued utility after the food is consumed. Therefore, FDA concludes that the nature of the container, i.e., its continued utility, may have a significant influence on container fill.

Most manufacturers try to market their products as attractively as possible. FDA finds that providing for slack-fill solely as a function of aesthetics is neither necessary nor appropriate. FDA believes that such an exception would cover a very broad and poorly defined range of packaging practices. Therefore, FDA denies the request.

Accordingly, FDA is modifying proposed § 100.100(a)(5) to specify that reasonable amounts of slack-fill resulting from the packaging of a food component in a reusable container, where the container is part of the presentation of the food and has

significant value independent of its function to hold the food, is not nonfunctional slack-fill. FDA finds that exempting reasonable amounts of slack-fill in products consisting of a food component and a reusable container will provide manufacturers with flexibility in packaging such products, when such flexibility is needed, and will provide consumers with product choices.

Slack-fill That Plays a Role in the Preparation or Consumption of a Food

16. One comment objected to that portion of proposed § 100.100(a)(4) that exempted slack-fill that performs a function in the preparation or consumption of a food from the definition of nonfunctional slack-fill "where such function is inherent to the nature of the food and is clearly labeled." The comment suggested that FDA modify proposed § 100.100(a)(4) to provide that such function must be either obvious or clearly labeled. In support of its position, the comment stated that it markets cereal in bowl-shaped containers. The comment stated that it is obvious to consumers that the bowl-shaped package not only contains their product but may also hold added milk and be used to eat the food. The comment maintained that when the function of the package is obvious, it is not necessary to explain it on the label.

FDA agrees that when the function of the slack-fill is obvious (e.g., a bowl-shaped food package that can be used to consume the food), it is not necessary to provide a label statement declaring the obvious. FDA notes that some products may be packaged so that consumers can clearly see the amount of product relative to other components of the packaging, such as a baking tray. For example, six, one-half cup, single-serving containers of pudding may be surrounded by an open-ended cardboard sleeve that allows consumers to view the size of the cups and to see that they can be used to consume the food. A box containing several packages of a dry seasoning mix for salad dressings and a glass bottle in which the dressings can be mixed and served may be designed to display the bottle and the smaller packages of seasoning mix.

On the other hand, many of the food products addressed by § 100.100(a)(4) are new and novel and may be unfamiliar to consumers. The number and range of these products are likely to increase with future advances in innovative packaging technologies and product development. For example, a package of microwavable brownies may contain a tray in which the brownies can be mixed and cooked. Thus the size

of the package is a function of the requirements of the baking tray, not the amount of product. Further, the convenience aspect of this product may include not only faster preparation but a smaller volume of product compared to a typical package of brownie mix intended to be cooked in a conventional oven.

FDA finds that slack-fill resulting from the need for a package to perform a specific function (e.g., to play a role in the preparation or consumption of a food), where such function is inherent to the nature of the food, is functional slack-fill. FDA also finds that the function of such packaging is a material fact in the purchase of the food product and must be communicated to the consumer. Therefore, FDA has modified proposed § 100.100(a)(4) to require that the function of such slack-fill be clearly communicated to the consumer.

17. Another comment requested that FDA amend proposed § 100.100(a)(4) to include minimum type size and placement requirements for statements explaining the function of the slack-fill. The comment suggested that FDA incorporate requirements similar to those established for net quantity declarations in 21 CFR 101.105(i).

FDA notes that under section 403(f) of the act, required information shall 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." Failure to comply with section 403(f) of the act renders a food misbranded. FDA also notes that 21 CFR 101.15 (§ 101.15) sets forth conditions under which required statements may be deemed to lack the appropriate prominence or conspicuousness. FDA has previously found (58 FR 2470 at 2473) that section 403(f) of the act is adequately implemented by FDA regulations.

The comment did not provide any basis on which to conclude that section 403(f) of the act and the implementing regulations in § 101.15(a) will not be adequate to ensure that information concerning the function of slack-fill in containers is clearly communicated to consumers, and that more specific type size and placement requirements are necessary. Therefore, FDA is not establishing specific requirements for type size or placement of statements related to the function of slack-fill within a container. However, should FDA determine, in its experience with new § 100.100(a)(4), that such requirements would improve implementation of § 100.100, it would

consider amending the regulation accordingly.

Dietary Supplements

18. One comment requested that slack-fill in dietary supplements be exempt from the definition of nonfunctional slack-fill because, according to the comment, consumers do not make the same types of value comparisons with respect to dietary supplements that they make for conventional food products. Therefore, according to the comment, consumers cannot be misled as to the amount of product they are purchasing.

FDA disagrees. The agency is not convinced by the comment that there is any reason to treat dietary supplements differently from other conventional food items. Some exceptions may be appropriate to this commodity class (e.g., the small package exemption); however, dietary supplements are food and, as such, must comply with section 403(d) of the act.

Test Products

19. Several comments suggested that FDA provide an exemption in § 100.100 for products that are being test marketed.

FDA is aware that a significant proportion of new products are introduced into the market place but are discontinued after a brief trial. FDA understands that there may be a reluctance on the part of some manufacturers to purchase new packaging equipment for a product whose future is uncertain. At the same time, FDA believes that if consumers are paying fair market price for test products, they deserve fair market value. Therefore, FDA finds that test product containers, like those of any other food product, must facilitate value comparisons and not be misleading.

Further, depending on the nature of the product and the size of the company, a test market may be quite extensive, e.g., involving a significant market share, distribution in all States, and an unlimited period of time. FDA expects manufacturers to examine their choice of packaging when preparing to introduce a new product into the market place. In some instances, such as the extension of an existing product line, current packaging practices may be appropriate for the new product (e.g., packaging related products on a single line as provided for within § 100.100(a)(2)). Therefore, FDA finds that it is not necessary or appropriate to exclude new products from the misleading container provisions in § 100.100.

Display Requirements

20. Several comments stated that FDA should modify proposed § 100.100(a) to recognize that some slack-fill may be a function of a package's display requirements. Examples of functions related to display requirements included package strength and stackability.

FDA advises that slack-fill resulting from the need for package strength is adequately provided for within § 100.100(a)(1) (protection of contents) as functional slack-fill. Therefore, FDA finds that no additional change is necessary with respect to package strength requirements.

FDA also advises that stackability is related more to the way in which a container is made or formed than it is to level of fill within the container. For example, containers may be formed so as to facilitate the bottom of one can resting on the lid of the can below. A bag may be designed with a pocket in its base to fit over the top of another bag. Both of the above examples refer to the way a container is made or formed, rather than filled. FDA also notes that there is a significant difference between, for example, a small recess at one end of a container that allows containers to be stacked and a large recess whose only function is to mislead consumers as to the quantity of contents in such container.

Further, to the extent that the conformation (i.e., shape and style) of the package influences the level of fill within the container, such slack-fill may be related to the requirements of the filling machine (§ 100.100(a)(2)) or to a minimum package size requirement (§ 100.100(a)(6)).

On the other hand, although increasing the size of a package may improve the stackability and display characteristics of the container, if such package contains nonfunctional slack-fill, the food is misbranded. Likewise, FDA finds that false bottoms or other devices that may incidentally improve display features would nonetheless render a food misbranded if such devices misled consumers as to the quantity of product in the container.

Thus, the comments did not provide a sufficient basis for FDA to conclude that it is either necessary or appropriate to provide for slack-fill that results solely from the display requirements of a container as functional slack-fill. Therefore, FDA denies the request.

K. Other Matters

Filled to Substantially Less Than Capacity

21. One comment stated that all slack-fill that is not provided for by the exceptions in § 100.100(a) is significant and potentially deceptive. The comment maintained that defining the term "significant" so that it is meaningful in all contexts is problematic and leaves a loophole in the definition of nonfunctional slack-fill that may be exploited. The comment also maintained that the phrase "substantially less" places an additional and unnecessary burden on regulatory officials to prove "significant or substantial" slack-fill. Therefore, the comment suggested that FDA delete the word "substantially" from the final regulation.

One comment suggested that FDA define "filled to substantially less than capacity" as those packages where one-third of their volume is empty space. Another comment maintained that the terms "substantially" and "significant" in the context of the proposed regulation are qualified, not only by volume but by value, visibility, method of sale, usable space, and labeling. The comment argued that both common sense and expertise must govern the interpretation of these terms on a case-by-case basis. The comment stated that FDA has taken action against fills as low as 44 percent and as high as 67 percent of capacity. The comment concluded that it knows of no rational basis for establishing a specific threshold for the amount of airspace that constitutes significant underfilling.

FDA recognizes that there is significant variability in the amount of slack-fill in packages, both between and within commodity classes and even within a single-product line. Factors that influence slack-fill include the physical characteristics of the product, the capabilities of the filling machine, and the way in which the product is handled. When FDA proposed to define "nonfunctional slack-fill" as the empty space in a package that is filled to substantially less than its capacity for reasons other than to accomplish a specific functional effect, the agency intended to exclude normal variations in level of fill from the definition of nonfunctional slack-fill.

FDA agrees with the comment that stated that no specific numerical value could adequately describe the amount of nonfunctional slack-fill that would be significant. For example, it is possible to package some products with essentially no slack-fill, while other products may have a significant amount of slack-fill to

allow package closure or to protect the product. FDA finds that the primary issue is whether slack-fill is functional versus nonfunctional. The amount of slack-fill becomes important when determining whether that amount of slack-fill in a container exceeds that which is necessary to accomplish a particular function. FDA did not intend to impose an additional regulatory burden with the use of this term, nor did it intend to provide a loophole for products containing nonfunctional slack-fill. Further, the record is clear that section 403(d) of the act is not meant to prohibit normal variations in fill based on the characteristics of a particular product or the capabilities of machines used to fill packages. Therefore, FDA is deleting the word "substantial" from § 100.100(a).

Downsizing

22. One comment disagreed with FDA's determination that it does not have jurisdiction over downsizing. The comment stated that, in its view, the misleading container provisions of section 403(d) of the act apply to downsizing. The comment defined "downsizing" or "package shorting" as the practice of filling a container such that the amount of product is reduced but the size of the container is unchanged. The comment stated that this practice is an increasingly common form of economic deception and is an increasing area of public concern. The comment further stated that section 403(a) of the act (false or misleading labeling) provides FDA with the authority to require that a food label disclose that a package has been downsized. The comment urged FDA to propose, in a separate Federal Register notice, regulations requiring such disclosure.

FDA believes that there is some confusion as to what constitutes downsizing, and what constitutes package shorting. Although these terms have been used interchangeably by some, they represent two different practices. Downsizing refers to the practice of reducing both the amount of product and the size of the container holding the product such that consumers may not be aware of these changes. For example, a manufacturer may decide, with an appropriate change in the net weight statement, to sell 4 oz of baby food in a new container that, although slightly smaller, is similar in appearance (e.g., same shape and graphics) to one that has traditionally held 5 oz. The price of the new product often remains the same as that of the larger container. Further, the new container may be designed in such a

way that the amount of slack-fill in relation to the amount of product in the container remains the same, i.e., without creating nonfunctional slack-fill. The potential problem with downsizing lies in the fact that consumers, familiar with a particular product and its packaging, may not be aware that the size of the container and the amount of product therein have been reduced and therefore, do not realize that they are purchasing a smaller amount of product.

Package shorting refers to reducing the amount of product in a container without reducing the volume of the container. For example, a manufacturer may decide to sell 6.8 oz of rice in the same container that previously held 8 oz, with an appropriate change in the net quantity of contents declaration. Again, consumers who are in the habit of purchasing a particular product and package size may assume they are getting the same amount of product that they are accustomed to purchasing.

FDA notes that reducing the amount of product in a container without reducing the volume of the container (i.e., package shorting) will increase the amount of slack-fill in that container. To the extent that some portion of this slack-fill would be nonfunctional, the practice would constitute misleading fill under § 100.100(a).

However, proliferation of sizes, of which downsizing may be a part, comes under the jurisdiction of the Department of Commerce as provided for in section 5(d) of the FPLA. Section 5(d) sets out procedures for developing voluntary product standards "[w]henver the Secretary of Commerce determines that there is an undue proliferation of weights, measures, or quantities in which any consumer commodity or reasonably comparable consumer commodities are being distributed in packages for sale at retail and such undue proliferation impairs the reasonable ability of consumers to make value comparisons * * *."

Therefore, package shorting that results in misleading fill is prohibited by section 403(d) of the act and its implementing regulations. However, any action under section 403(a) of the act to require label statements informing consumers that a container has been downsized is outside the scope of this rulemaking and would need to be addressed in a future rulemaking.

IV. Conclusion

Therefore, FDA is promulgating new § 100.100 (21 CFR part 100.100), in new subpart F of Part 100 (Subpart F—Misbranding for Reasons Other Than Labeling). The regulation states that

food is misbranded if its container is so made, formed, or filled as to be misleading. It defines nonfunctional slack-fill in containers that do not allow consumers to fully view their contents by setting forth criteria for determining whether slack-fill is functional or nonfunctional.

As stated in section II. of this preamble, the agency anticipates that this final rule will supersede the regulation that was considered final by operation of law on May 10, 1993. Elsewhere in this issue of the Federal Register, FDA is proposing to revoke the May 10, 1993, regulation.

The agency finds that the new regulation adequately implements section 403(d) of the act and thus provides additional consumer protection against misleading fill and facilitates value comparisons on the part of consumers.

This regulation will also provide State regulatory agencies, as well as FDA, with a uniform means of taking action against misleading containers. Section 4 of the 1990 amendments provides for State enforcement of section 403(d) of the act in Federal court. Consequently, manufacturers can expect that packaging will be treated uniformly throughout the States with regard to misleading containers.

V. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (58 FR 2957 at 2963). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. Economic Impact

FDA has examined the economic implications of the final rule on misleading containers and nonfunctional slack-fill as required by Executive Orders 12866 and 12612 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 compels agencies to use cost-benefit analysis when making decisions, and Executive Order 12612 requires Federal agencies to ensure that Federal solutions, rather than State or local solutions, are necessary. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. The agency finds that this final rule is not a major rule as defined by Executive Order 12866. In accordance with the Regulatory Flexibility Act, FDA has also determined that this final rule will not have a significant adverse impact on a

substantial number of small businesses. Finally, any federalism issues that would require an analysis under Executive Order 12612 are resolved as a matter of law by section 6 of the 1990 amendments.

A. Costs

This final rule prohibits only nonfunctional slack-fill. Industry comments presented situations in which slack-fill might be considered functional. As indicated in the preamble, many of these situations fall under, and are addressed by, exemptions to the definition of "nonfunctional slack-fill" that were included in the proposal. In addition to the examples given in the preamble, slack-fill that is necessary for the following reasons is 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.

However, other situations in which industry comments suggested slack-fill might be functional or nonmisleading have not been exempted. For example, the agency has not provided an exemption for products sold through vending machines or for gift packages where the container is not reusable or durable.

In addition, FDA has not provided exemptions based solely on lowering the economic impact of the final rule, including packaging for test products or for exotically shaped products which require nonstandard packaging. Finally, FDA has no basis to address the issue of whether it would be necessary or appropriate to grant any exemptions for small businesses as discussed in the economic impact section of the misleading container proposal (58 FR 2957 at 2963).

FDA has insufficient information to quantify the reduction in compliance costs that would occur if these additional exemptions were granted; however, FDA believes the reduction in costs would be small.

B. Benefits

FDA received no information allowing it to estimate the benefit of reducing the incidence of differing interpretations of the language of section 403(d) of the act that might occur if FDA had merely promulgated a regulation that repeats the language of section 403(d). In addition, FDA has received no information that enabled it to estimate the benefit to consumers of the possible reduction in the incidence

of consumer dissatisfaction with the fill of food containers or that enabled it to estimate the effect of granting additional exemptions on the possible reduction in consumer dissatisfaction.

C. Conclusion

Although unable to quantify the costs and benefits of this final rule, FDA believes they are probably small. As stated in section II. of this document, FDA finds that no hardship will result from replacing the May 10, 1993, regulation with this final rule.

List of Subjects in 21 CFR Part 100

Administrative practice and procedure, Food labeling, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 100 is amended as follows:

PART 100—GENERAL

1. The authority citation for 21 CFR part 100 continues to read as follows:

Authority: Secs. 201, 301, 307, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 337, 342, 343, 348, 371).

2. New subpart F, consisting of § 100.100, is added to read as follows:

Subpart F—Misbranding for Reasons Other Than Labeling

§ 100.100 Misleading containers.

In accordance with section 403(d) of the act, a food shall be deemed to be misbranded if its container is so made, formed, or filled as to be misleading.

(a) A container that does not allow the consumer to fully view its contents shall be considered to be filled as to be misleading if it contains nonfunctional slack-fill. Slack-fill is the difference between the actual capacity of a container and the volume of product contained therein. Nonfunctional slack-fill is the empty space in a package that 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;
- (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, e.g., a gift product consisting of a food or foods combined with a container that is intended for further use after the food is consumed; or durable commemorative or promotional packages; or

(6) Inability to increase level of fill or to further reduce the size of the package (e.g., where some minimum package size is necessary to accommodate required food labeling (excluding any vignettes or other nonmandatory designs or label information), discourage pilfering, facilitate handling, or accommodate tamper-resistant devices).

(b) [Reserved]

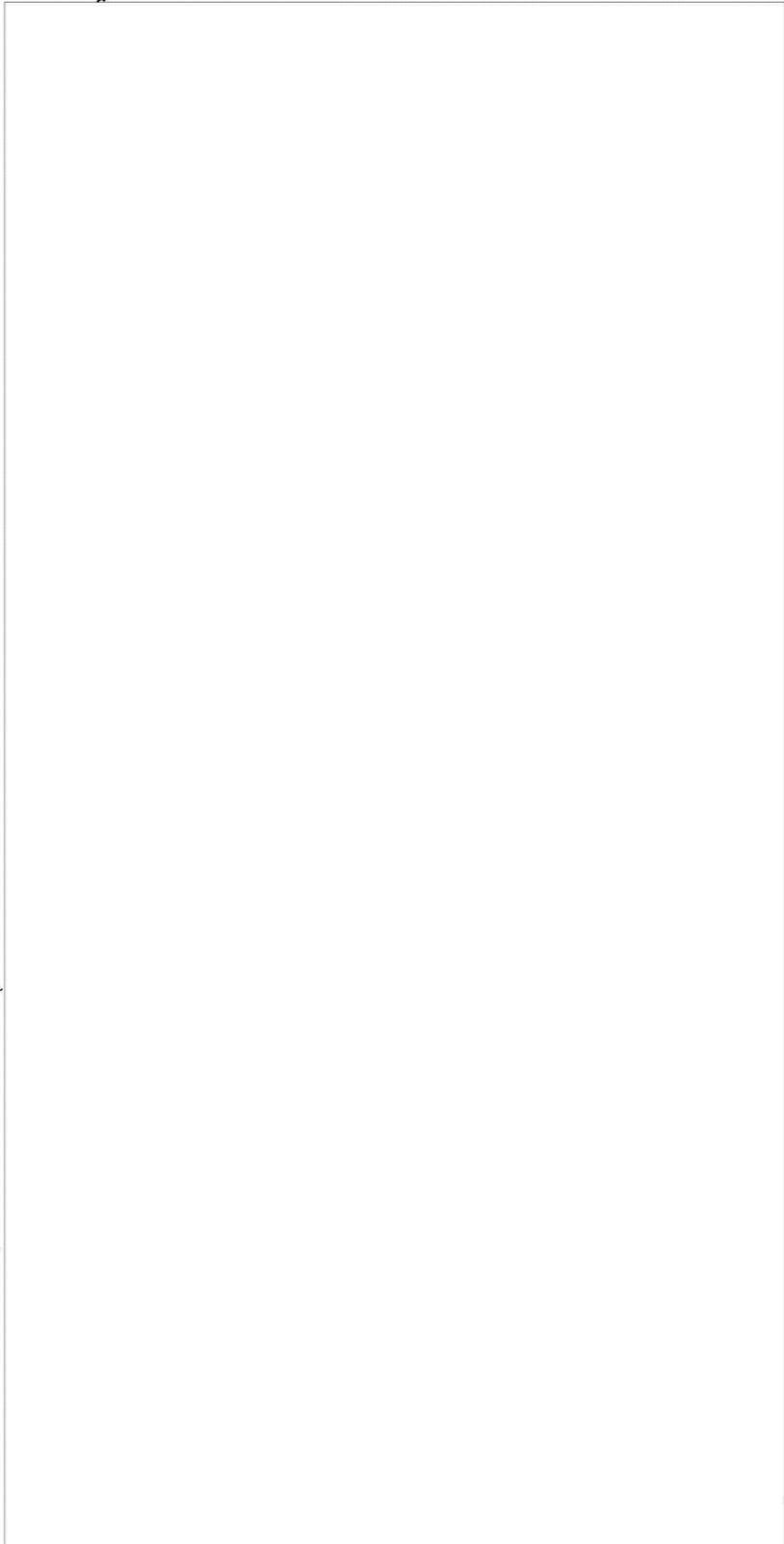
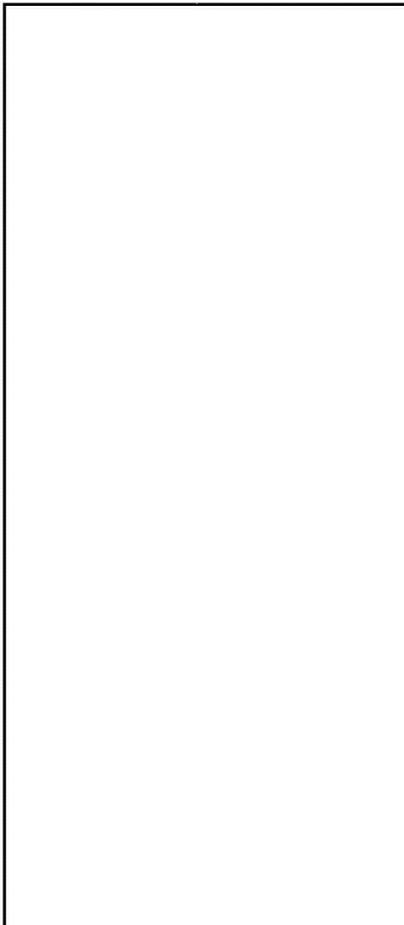
Dated: November 30, 1993.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 93-29690 Filed 12-3-93; 8:45 am]

BALING CODE 4160-01-F



APPENDIX: 2

Examples of Court Decisions and Complaints Filed Related to Slack-Fill Allegations, 2017-2018

Court Decisions:

1. *Miao Xin Hu v. Iovate Health Scis. U.S.A. Inc.*, No. 17 CIV. 09427 (ER), 2018 WL 4954105 (S.D.N.Y. Oct. 12, 2018): Plaintiff alleged that Herbal Zen’s plant-based protein powder was packaged with an unlawful amount of nonfunctional slack-fill under sections 349 and 350 of New York’s General Business Law based on a comparison to a different product that had a smaller amount of slack-fill. The Court granted Defendant’s motion to dismiss because the product in question clearly stated the weight of the product, and thus “the allegedly nonfunctional slack-fill would not mislead a reasonable consumer acting reasonably under the circumstances.”
2. *Yee Ting Lau v. Pret A Manger (USA) Ltd.*, No. 17-CV-5775 (LAK), 2018 WL 4682014 (S.D.N.Y. Sept. 28, 2018): Plaintiffs alleged fraud and violations of sections 349 and 350 of New York’s General Business Law (NYGBL) on the basis that Defendant’s packaging of its pre-made wrap products concealed non-functional slack fill and thus “misleads consumers about the amount of wrap they receive for the price charged.” The Court dismissed the fraud claim, finding that Plaintiffs had not provided sufficient evidence to prove intent to defraud, but permitted the claims under the NYGBL to proceed, finding that Plaintiffs were injured by Defendant’s packaging practices.
3. *Spacone v. Sanford, LP*, No. CV1702419BROMRWX, 2017 WL 6888497 (C.D. Cal. May 11, 2017): Plaintiff alleged violation of the Fair Packaging and Labeling Act (Cal. Bus. & Prof. C. § 12606(b)) on the basis that the product, Krazy Glue, was packaged with a “larger opaque container that housed the tube...[that] led him to believe that the package contained more adhesive than it actually did.” The Court denied Defendant’s motion to dismiss, stating that even though the product packaging’s contained an accurate display of its weight, a reasonable consumer could have been misled. The Court later denied class certification in *Spacone v. Sanford, L.P.*, No. 2:17-CV-02419-AB-MRW, 2018 WL 4139057 (C.D. Cal. Aug. 9, 2018).
4. *White v. Just Born, Inc.*, No. 2:17-CV-04025-C-NKL, 2017 WL 3130333 (W.D. Mo. July 21, 2017); class certification denied in *White v. Just Born, Inc.*, No. 2:17-CV-04025-NKL, 2018 WL 3748405 (W.D. Mo. Aug. 7, 2018): Plaintiff brought suit against the manufacturer of Hot Tamales and Mike and Ike candies under the Missouri Merchandising Practices Act (MMPA), alleging that the size of the packaging suggested Plaintiff was purchasing more candy than the packages actually contained. The Court denied Defendant’s motion to dismiss, finding that Plaintiff had adequately pled “(1) the purchase of goods or services, (2) primarily for personal or household purposes; and (3) an ascertainable loss of money or property, (4) as a result of, or caused by, the

use or employment by another person of a method, act, or practice declared unlawful under the MMPA.” Following notice that the parties had reached a settlement agreement, the Court dismissed the case on November 14, 2018.

5. *Daniel v. Tootsie Roll Indus., LLC*, No. 17 CIV. 7541 (NRB), 2018 WL 3650015 (S.D.N.Y. Aug. 1, 2018): Plaintiffs claimed, under sections 349 and 350 of New York’s General Business Law or common law fraud, that Defendant’s opaque boxes of Junior Mints candies contained “non-functional slack-fill” that mislead consumers as to the amount of product contained therein. New York law, the Court explained, requires the plaintiff to show that a reasonable consumer would find the misrepresentation from the slack-fill to be material. Based on “the prominence with which the Products’ weight appears on the front of the package, the ease with which consumers can calculate the number of candies contained therein, consumers’ expectations of slack-fill, as well as plaintiffs’ conceded reliance on factors other than the Products’ packaging,” the Court found that no reasonable consumer would be misled and thus granted Defendant’s motion to dismiss.
6. *Macaspac v. Henkel Corp.*, No. 3:17-CV-01755-H-BLM, 2018 WL 2539595 (S.D. Cal. June 4, 2018): Plaintiff alleged that the packaging of Purex Crystals in-wash fragrance booster product was deceptive and misleading, bringing claims under several California consumer protection statutes (California’s Consumer Legal Remedies Act, Cal. Civ. Code § 1750 et seq., Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, et seq., and False Advertising Law, Cal. Bus. & Prof. Code § 17500, et seq.). The Court explained that Plaintiff’s unfair competition claim was predicated on Cal. Bus. & Prof. C. § 12606. The Court dismissed Plaintiff’s complaint on the basis that no reasonable consumer would be deceived because product’s packaging enabled consumers to view the contents of the package without opening the lid, altering the packaging, or damaging the product.
7. *Alce v. Wise Foods, Inc.*, No. 17 CIV. 2402 (NRB), 2018 WL 1737750 (S.D.N.Y. Mar. 27, 2018): Plaintiff brought suit against potato chip manufacturer, alleging under New York law (New York’s General Business Law §§ 349 and 350) and District of Columbia law (D.C. Code § 28-3904(a), (e), (h), and (x)) that the packaging of Defendant’s products misled consumers into purchasing bags of chips with far fewer chips than they believed were present in each bag. In granting Defendant’s motion to dismiss, the Court concluded that Plaintiffs had not met their burden to allege that the slack-fill in Defendant’s products was non-functional, or that the slack-fill would mislead a reasonable consumer. In reaching the latter conclusion, the Court explained that the weight of the potato chips was displayed on the exterior of the package and that consumers expect significant slack-fill in potato chips and other snack products.
8. *Benson v. Fannie May Confections Brands, Inc.*, No. 17 C 3519, 2018 WL 1087639 (N.D. Ill. Feb. 28, 2018): Plaintiffs alleged, under the Illinois Consumer Fraud and Deceptive Business Practices Act (ICFA), 815 Ill. Comp. Stat. 505/1 et seq., that candy products (Mint Meltaways and Pixies), sold in opaque boxes, contained a significant amount of slack-fill that is misleading to consumers. However, the Court granted Defendant’s motion to dismiss (without prejudice),

because Plaintiffs failed to adequately allege that the slack-fill was nonfunctional in violation of 21 C.F.R. § 100.100(a).

9. *Daniel v. Mondelez Int'l, Inc.*, 287 F. Supp. 3d 177 (E.D.N.Y. 2018): Plaintiff filed putative class action suit under New York law (New York's General Business Law §§ 349 and 350), alleging that Defendant's Swedish Fish candy product packaging misrepresents the amount of food contained therein. The Court granted Defendant's complaint without prejudice, concluding that "a reasonable consumer acting reasonably would find accurate, clearly visible representations of net weight, serving size, and number of servings to offset any misrepresentations arising from non-functional slack-fill."
10. *Hawkins v. Nestle U.S.A. Inc.*, 309 F. Supp. 3d 696 (E.D. Mo. 2018): Plaintiff alleged that Defendant's Raisinets products were deceptive under the Missouri Merchandising Practices Act (MMPA) because the packaging contained an amount of slack-fill space that misled her into believing that the boxes contained more candy than they actually did. The Court denied Defendant's motion to dismiss, finding that whether the amount of slack-fill would be expected by a reasonable consumer is an issue of fact that could not be resolved on a motion to dismiss. Notably, the Court also rejected Defendant's claim that no reasonable consumer would be deceived because the candy box contained "clear and accurate labeling on the packages" (net weight, number of pieces of candy per serving, and number of servings per box), finding instructive the fact pattern and rationale from *Murphy v. Stonewall Kitchen, LLC*, 503 S.W.3d 308 (Mo. App. 2016).
11. *Bratton v. Hershey Co.*, No. 2:16-CV-4322-C-NKL, 2017 WL 2126864 (W.D. Mo. May 16, 2017): Plaintiff alleged that Defendant's Reese's Pieces and Whoppers candies products were deceptive under the Missouri Merchandising Practices Act (MMPA) because the packaging contained an amount of slack-fill space that misled him into believing that the boxes contained more candy than they actually did. The Court denied Defendant's motion to dismiss, finding that whether the amount of slack-fill would be expected by a reasonable consumer is an issue of fact that could not be resolved on a motion to dismiss. The Court noted that in other jurisdictions, "courts that have allowed slack-fill, consumer protection cases to proceed beyond the motion to dismiss stage tend to do so because reasonableness was at issue and could not be resolved short of summary judgment or trial." The Court ultimately granted summary judgment to Defendant, finding that Plaintiff was aware of the amount of slack-fill in the containers and purchased them anyway, and thus was not injured by Defendant's purportedly deceptive practice. *Bratton v. Hershey Co.*, No. 2:16-CV-4322-C-NKL, 2018 WL 934899 (W.D. Mo. Feb. 16, 2018).
12. *Wurtzburger v. Kentucky Fried Chicken*, No. 16-CV-08186 (NSR), 2017 WL 6416296 (S.D.N.Y. Dec. 13, 2017): With regard to slack-fill, Plaintiffs complaint asserted, under sections 349 and 350 of New York's General Business Law, that "the bucket of chicken Plaintiff purchased could hold more chicken than the eight-pieces Plaintiff bargained for." The Court dismissed Plaintiff's complaint, finding that Plaintiff failed to provide factual support for her claim that Defendant used slack-fill in a manner outside the enumerated purposes in 21 C.F.R. § 100.100(a)(1)-(6).

13. *Martin v. Wm. Wrigley Jr. Co.*, No. 4:17-CV-00541-NKL, 2017 WL 4797530 (W.D. Mo. Oct. 24, 2017): Plaintiff claimed, under the Missouri Merchandising Practices Act (MMPA), that Defendant's gum product conceals that the blister-pack gum sheet conceals empty tabs that give the appearance of additional gum pieces. The Court dismissed the complaint, with prejudice, finding it impossible that a consumer would reasonably believe the packaging to be misleading because: (1) the empty space is clearly visible to the purchaser without manipulating the packaging, and (2) the packaging clearly states the number of pieces of gum contained in the product.
14. *Gordon v. Tootsie Roll Indus., Inc.*, No. CV172664DSFMRWX, 2017 WL 8292777 (C.D. Cal. July 31, 2017); *Gordon v. Tootsie Roll Indus., Inc.*, No. CV172664DSFMRWX, 2017 WL 4786090 (C.D. Cal. Oct. 4, 2017) (granting motion to dismiss with regard to additional products except Sugar Babies and Junior Mints candies): Plaintiff claimed that because it was only 55% full, a box of Junior Mints misrepresented the amount of candy contained within, in violation of various California consumer protection laws (California Consumers Legal Remedies Act (CLRA), California False Advertising Law (FAL), and California Unfair Competition Law (UCL)). The Court denied Defendant's motion to dismiss, finding that Plaintiff had pled sufficient facts showing that (1) the packaging may deceive a reasonable consumer, and (2) the Junior Mint's packaging contained non-functional slack-fill.
15. *Stewart v. Riviana Foods Inc.*, No. 16-CV-6157 (NSR), 2017 WL 4045952 (S.D.N.Y. Sept. 11, 2017): Plaintiff alleged that Defendant had packaged its healthy line of pastas to contain "only 12 ounces of healthy pasta in "the same iconic boxes" traditionally sized and priced to contain 16 ounces (i.e., one pound) of product, as to induce consumers into paying a premium for healthy pasta without realizing that they are purchasing less product," in contravention of New York's General Business Law §§ 349 and 350. The Court was persuaded by Defendant's argument that "consumers who expect to receive 16 ounces of healthy pasta 'solely because she has purchased different Ronzoni pasta products in similarly-sized boxes,' is not reasonable," and pointed to clear packaging differences between the "healthy" and "traditional" lines of pasta products (in addition to price and weight differences).
16. *Escobar v. Just Born Inc.*, No. CV1701826BROPJWX, 2017 WL 5125740 (C.D. Cal. June 12, 2017): Plaintiff alleged that Defendant's candy products, Mike and Ike and Hot Tamales, contained 46% non-functional slack-fill, and as a result would mislead consumers as to the actual volume of product being purchased while providing Defendant with financial benefit due to lower supply costs. The Court denied Defendant's motion to dismiss, finding that Plaintiff: (1) had alleged facts indicating that a reasonable consumer would be deceived by product's packaging; (2) can plausibly allege deception on the basis of 21 C.F.R. § 100.100; (3) adequately pleaded facts to show that the products contained non-functional slack-fill; and (4) the claims were pleaded with particularity (as to this point, the Court explains that "although Plaintiff does not specify the particular address or date on which she purchased the Products, district courts in this Circuit have held that allegations that a misleading statement was made throughout the class period satisfy the [...] particularity standard.").

17. *Kline v. Iovate Health Scis. U.S.A., Inc.*, No. 3:15-CV-02387, 2017 WL 1135580 (S.D. Cal. Mar. 27, 2017): Plaintiffs brought complaint against Defendant under New York and California laws, alleging that it intentionally packages its products in opaque containers comprised of more than 40% non-functional slack-fill. The Court dismissed Plaintiffs' claims under California's False Advertising Law, Cal. Bus. & Prof. Code § 17500 et seq., and California Legal Remedies Act, Cal. Civ. Code § 1750 et seq., as time barred, and claims under California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 et seq., as insufficient to meet the heightened standard for alleging fraud under FRCP Rule 9(b). It also dismissed Plaintiffs' negligent misrepresentation claims because no special relationship was alleged. However, the Court allowed non-functional slack-fill claims (alleged as violations of New York Deceptive Trade Practices Act (DTPA), New York Gen. Bus. Law § 349, and Cal. Bus. & Prof. Code § 12606) to proceed.
18. *Martinez-Leander v. Wellnx Life Scis., Inc.*, No. CV 16-08220 SJO (EX), 2017 WL 2616918, at *1 (C.D. Cal. Mar. 6, 2017): Plaintiff alleges that Defendant's Nature's Science 100% Pure Garcinia Cambogia and Phytogenix Laboratories Ultimate Garcinia Cambogia herbal supplement products are packaged with deceptive non-functional slack fill because they are sold in bottles that constitute less than half the volume of the opaque outer box and bottles are slack-filled such that the herbal supplements constitute less than half of the bottle. Ultimately, Plaintiffs allege that the herbal supplements comprise less than 23% of the total volume of the boxes in which they are sold. The Court dismissed Plaintiffs' claims, with leave to amend, on the grounds that Plaintiffs failed to provide sufficient facts to show either that the slack-fill was non-functional or that a reasonable consumer could have been misled by the packaging.

Complaints Filed:

19. *Reaves v. BFY Brands, Inc.*, No. 7:18-cv-02065 (NSR) (S.D.N.Y. 2018): Plaintiff alleged that Our Little Rebellion Popcorners chip products were packaged with a large amount (around 54%) of nonfunctional slack-fill in violation of New York General Business Law § 349 and 350. Plaintiff also brought a claim in common law fraud. The case was voluntarily dismissed on July 25, 2018.
20. *Kpakpoe-Awei v. Storck USA, L.P.*, No. 7:18-cv-01086 (VLB) (S.D.N.Y. 2018): Plaintiff alleged that Werther's Original Sugar Free Chewy Caramels (2.75 oz) were packaged with a large amount (around 69%) of nonfunctional slack-fill in violation of New York General Business Law § 349 and 350. Specifically, Plaintiff argues that Defendant uses the same size packaging for the same product in a 5 oz amount, and that the 5 oz product contains substantially less slack-fill. Plaintiff also alleges a claim under common law fraud. The Court dismissed the case on June 8, 2018, after the parties advised that they had reached a settlement.
21. *Buso v. ACH Food Companies Inc.*, No. 3:17-cv-01872-JAH-MDD (S.D. Cal. 2017): Plaintiff alleged that Fleischmann's Simply Homemade Baking Mix Cornbread product contained more than 50% nonfunctional slack-fill, in violation of California's False Advertising Law, Cal. Bus. & Prof. Code § 17500 et seq., California Legal Remedies Act, Cal. Civ. Code § 1750 et seq., and California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200. Although Defendant filed a motion to

dismiss on November 2, 2017, the Court has yet to issue a ruling on that motion and the case remains pending.

22. *Buso v. Just Born, Inc.*, No. 3:17-cv-01630-JAH-JMA (S.D. Cal. 2017): Plaintiff alleged that Mike and Ike's Original Fruit candy product contained approximately 30% nonfunctional slack-fill, in violation of California's False Advertising Law, Cal. Bus. & Prof. Code § 17500 et seq., California Legal Remedies Act, Cal. Civ. Code § 1750 et seq., and California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17200. On October 18, 2017, the parties jointly requested dismissal, which the Court granted, without prejudice, on October 26, 2017.
23. *Brown v. Harry and David, LLC*, No. 1:17-cv-00999 (DAB) (S.D.N.Y. 2017): Plaintiff alleged that Moose Munch gourmet popcorn product contained an excess of nonfunctional slack-fill, in violation of New York General Business Law § 349 and 350. Plaintiff also brought a claim in common law fraud. The case was voluntarily dismissed on March 22, 2017.