DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 17 2001

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The Honorable Joseph I. Lieberman
United States Senate
Washington, D.C. 20510-0703

Dear Senator Lieberman:

Thank you for your letter of July 2, 2001, on behalf of your constituent, Mr. Syd Aronowitz of Bethel, Connecticut, regarding the labeling of food products containing gluten. Mr. Aronowitz suffers from celiac disease, which causes intolerance to the protein component of the gluten in wheat, barley, rye, and oats. This means he needs to avoid food products containing these grains. He asks that food labels provide information on the source of the ingredients.

The Food and Drug Administration (FDA or the Agency) appreciates the difficulties faced by persons with food allergies and food intolerances. We have enclosed a Notice to Manufacturers that FDA distributed to food manufacturers, trade associations, and other food industry groups. It outlines steps to ensure that allergens are declared on food labels.

In the Notice, we ask manufacturers to examine their product formulations for known allergens and to be sure to declare the presence of these ingredients in the ingredient statement on the label. Please note that wheat is included in the list of common allergens. We believe that the inclusion of wheat in the list will help enable persons who have a gluten intolerance to avoid many products containing gluten.

By way of background, the Federal Food, Drug, and Cosmetic (FD&C) Act requires, in virtually all cases, that labels of food fabricated from two or more ingredients bear a declaration of each ingredient, by its common or usual name, in descending order of predominance by weight in the ingredient statement. There are two very narrow exemptions from this ingredient-labeling requirement. The first is provided in section 403(i) of the FD&C Act. That section

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states that spices, flavorings, and certain colorings may be declared collectively without naming each one.

The second is provided in Title 21, Code of Federal Regulations § 101.100(a). It states that incidental additives, such as processing aids that are present at insignificant levels and that do not have a technical or functional effect in the finished food, do not have to be declared on the label. Since evidence suggests that some allergenic substances can cause serious allergic responses in some individuals upon ingestion of very small amounts, FDA's Notice advised manufacturers that an allergen cannot be determined to be present at an insignificant level and therefore does not qualify for an exemption.

FDA has been working with industry and consumer groups to raise awareness about the presence of allergens in foods and to identify practical approaches for the labeling of allergens. Addressing food allergen issues has been identified as a priority this year by FDA's Center for Food Safety and Applied Nutrition (CFSAN). Specifically, CFSAN held a public meeting this month and plans to develop a strategy for exploring clearer labeling of food allergens.

Importantly, CFSAN has received and is currently reviewing petitions that raise concerns similar to those of Mr. Aronowitz. We have forwarded your correspondence to the docket for this matter for inclusion in the record (Docket #00P-1322). Please be assured that we will consider all comments before making a final decision on this issue.

For your information, we have enclosed a recent article entitled, "Food Allergen Awareness: An FDA Priority" that may be of interest to Mr. Aronowitz.

Thanks again for contacting us regarding this matter. If you have further questions, please let us know.

Sincerely,

Kristina Harper

for Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosures

cc: Dockets Management Branch (HFA-305)
(Docket No. 00P-1322)

JOSEPH I. LIEBERMAN
CONNECTICUT

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July 2, 2001

Dr. Bernard Schwetz
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Schwetz:

I'm enclosing a copy of a letter which I recently received from one of my constituents, Syd Aronowitz, who suffers from Celiac disease and who supports stronger labeling requirements on food products that contain gluten.

I would greatly appreciate it if you would provide me with a response which addresses the concerns my constituent has raised.

Thank you for your attention to this matter.

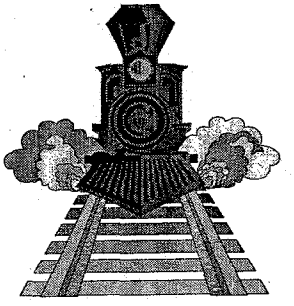
Sincerely,

Joseph I. Lieberman

JIL:vh
Enclosure

01-3468

SYD ARONOWITZ



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203 - 794 - 0150
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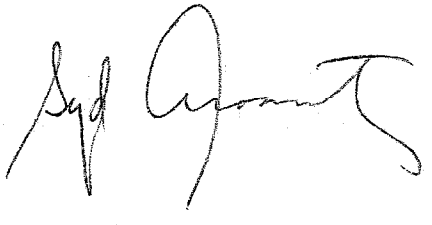
June 27,2001

Senator Joseph Lieberman
Washington, DC 20510-0703

Stronger Labeling requirements

I am a Celiac and cannot handle gluten. Gluten comes from Wheat, Barley, Oats and Rye. When this bill comes up PLEASE Vote for much stronger labeling. The label should state where the ingredience are derived from. This is the only way we CELIACS would know that it's safe. Today almost everyone has some type of intolerance, milk,nuts,wheat etc
Please include GLUTEN on the label.. I thank you for your support.

Syd Aronowitz
Bethel, CT 06801



U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
June 10, 1996

NOTICE TO MANUFACTURERS

Label Declaration of Allergenic Substances in Foods

This letter is to make you aware of the Food and Drug Administration's (FDA's) concerns regarding the labeling of foods that contain allergenic substances. Recently, FDA has received a number of reports concerning consumers who experienced adverse reactions following exposure to an allergenic substance in foods. These exposures occurred because the presence of the allergenic substance in the food was not declared on the food label.

The Food, Drug, and Cosmetic Act (the act) requires, in virtually all cases, a complete listing of all the ingredients of a food. Two of the very narrow exemptions from ingredient labeling requirements appear to have been involved in a number of the recent incidents, however. First, section 403(i) of the act provides that spices, flavorings, and colorings may be declared collectively without naming each one. Secondly, FDA regulations (21 CFR 101.100(a)(3)) exempt from ingredient declaration incidental additives, such as processing aids, that are present in a food at insignificant levels and that do not have a technical or functional effect in the finished food.

In some of the instances of adverse reactions, failure to declare an ingredient appears to have been the result of a misinterpretation of the exemption from ingredient declaration provided for incidental additives in 101.100(a)(3). FDA reminds manufacturers that to qualify for the exemption from ingredient declaration provided for incidental additives and processing aids, a substance must meet both of the requirements of 101.100(a)(3), i.e., it must be present in the food at an insignificant level, and it must not have any technical or functional effect in the finished food. Thus, incidental additives may include substances that are present in a food by virtue of their incorporation as an ingredient in another food. However, when an ingredient added to another food continues to have an effect in the finished food (e.g., egg white as a binder in breading used on a breaded fish product), the ingredient is not an incidental additive, and its use must be declared on the label.

The recent adverse reaction reports indicate that some manufacturers have also incorrectly interpreted what constitutes an insignificant level of a substance. Clearly, an amount of a substance that may cause an adverse reaction is not insignificant. Because evidence suggests that some allergenic substances can cause serious allergic responses in some individuals upon ingestion of very small amounts of the substance, it is unlikely that such an allergen, when it is present in a food, can be present at an insignificant level. Thus, it follows that the

requirements of 101.100(a)(3) can not be met under such circumstances.

FDA is considering whether it is necessary to clarify its regulations to ensure that manufacturers fully understand the circumstances in which allergenic food ingredients must be declared and to ensure that sensitive individuals are protected by appropriate labeling.

We have also received reports of adverse reactions to foods in which likely allergenic substances were used as flavors, and not declared by name. Therefore, in addition to the exemption in 101.100(a)(3), the agency is also considering whether an allergenic ingredient in a spice, flavor, or color should be required to be declared, 403(i) not withstanding. On a substance-by-substance basis, the agency has required ingredients covered by the exemption in section 403(i) to be declared when necessary to protect individuals who experience adverse reactions to the substance, e.g., FD&C Yellow No. 5. The agency is open to suggestions on how to best address this problem.

While FDA has not formally defined "allergens," it provided examples of foods that are among the most commonly known to cause serious allergenic responses, i.e., milk, eggs, fish, crustacea, mollusks, tree nuts, wheat, and legumes (particularly peanuts and soybeans), in a policy statement dealing with foods derived from new plant varieties published in the FEDERAL REGISTER of May 29, 1992 (57 FR 22984 at 22987).

FDA advises that the issue of declaring allergenic ingredients in food is being discussed on an international level. Several individual governments and the Codex Alimentarius Commission have begun to formulate policy for the labeling of foods containing allergenic ingredients to ensure that consumers are provided sufficient information to avoid substances to which they are allergic. While packaged foods sold in the U.S. are among the most comprehensively labeled foods in the world (some countries provide broader exemptions from ingredient declaration), FDA is studying its labeling requirements, and considering whether rulemaking is necessary, for the labeling of allergenic ingredients.

While the agency does so, FDA asks manufacturers to examine their product formulations for ingredients and processing aids that contain known allergens that they may have considered to be exempt from declaration as incidental additives under 101.100(a)(3), and to declare the presence of such ingredients in the ingredient statement. Where appropriate, the name of the ingredient may be accompanied by a parenthetical statement such as "(processing aid)" for clarity.

The voluntary declaration of an allergenic ingredient of a color, flavor, or spice could be accomplished by simply naming the allergenic ingredient in the ingredient list. Because such ingredients are normally present at very low levels, the name of the ingredient could generally be placed at the end of the ingredient list and be consistent with its descending order of predominance by weight. Other, non-allergenic ingredients t hat are exempt from declaration would remain unlisted.

Another area of concern is the potential, inadvertent introduction of an allergenic ingredient to a food (e.g., in a bakery that is manufacturing two food products on one production line, one product with peanuts and one without, where traces of peanuts, or peanut products, may

end up in the product that does not normally contain peanuts). FDA is considering options for providing consumers with information about the possible presence of allergens in these foods.

The agency is aware that some manufacturers are voluntarily labeling their products with statements such as "may contain (insert name of allergenic ingredient)." FDA advises that, because adhering to good manufacturing practice (GMP) is essential for effective reduction of adverse reactions, such precautionary labeling should not be used in lieu of adherence to GMP. The agency urges manufacturers to take all steps necessary to eliminate cross contamination and to ensure the absence of the identified food. The agency is open to suggestions on how best to address this issue.

Sincerely,

Fred R. Shank, Ph.D.

Director, Center for Food Safety and Applied Nutrition

Home

Hypertext maintained by LRD, DMS, et. al. (last updated on 5/30/97)

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
February-March 2001

Food Allergen Awareness: An FDA Priority

New initiatives focus on allergens in 2001.

Authors

Reprinted from *Food Safety Magazine* February-March 2001 issue

(Also available in PDF format)

As part of the public health mission to keep food safe, the U. S. Food and Drug Administration (FDA) is increasing its activity on food allergen awareness. FDA's 2001 allergen priorities for the Center for Food Safety and Applied Nutrition (CFSAN) describe new initiatives.[1] For example, a major goal is to provide guidance to industry and regulators on how to manage allergens through appropriate manufacturing and labeling practices.

For sensitive individuals, the presence of allergens in food is potentially life-threatening. Currently, there is no cure for food allergy. The only successful method to manage food allergy is avoidance of foods containing the allergen. Fortunately, most consumers are aware of their specific sensitivities and can avoid foods that might result in a life-threatening situation. For example, a person with a peanut allergy may find it easy to avoid whole peanuts. Formulated foods, however, present a separate challenge. In such cases, the individual relies on accurate ingredient labeling. The FDA, food manufacturers and special interest groups are working to increase public awareness of the seriousness of allergic reactions and to assure that allergens are appropriately labeled in food products.[2] For example, one of the U. S. Department of Health and Human Services' "Healthy People 2010" initiatives for the coming decade is to reduce the number of deaths due to anaphylaxis caused by food allergens.[3]

Allergic reactions are reported to be caused by a large variety of foods, and in theory, any food protein is capable of causing an anaphylactic reaction.[4] Agency allergen awareness efforts currently focus on the eight foods that are most frequently implicated in serious allergic responses: milk, eggs, fish, wheat, tree nuts, legumes

(particularly, peanuts and soybeans), crustaceans and mollusks.[1] Allergenic proteins in these eight foods are estimated to cause 90% of the allergic reactions in the U. S.[5] Some of these foods, such as milk and eggs, are often used as added ingredients in formulated products. Low amounts of these proteins may elicit a response and reactions may vary from mild to life-threatening, depending on a person's particular sensitivity. (Other substances, such as FD&C Yellow No. 5, sulfites and carmine/cochineal extract, also may cause allergic or allergic-type reactions.)

The number of allergic individuals in the U. S. is unknown. Estimates suggest, however, that 1.5% of the adult population and 5% of children younger than three years old have some form of food allergy.[6] One estimate of the number of fatal food anaphylaxis cases in the U. S. is 125 per year.[4]

THE INGREDIENT LABEL: ALERT FOR THE ALLERGY-SENSITIVE PERSON

The Federal Food, Drug, and Cosmetic Act (FD&C) requires, in virtually all cases, a complete listing of all the ingredients of a food on the food label. In certain cases, such as with allergens, public health concerns have been noted as FDA took steps to require particular wording in an ingredient statement. For example, 21 *Code of Federal Regulations* (CFR) 102.22 requires the food source identification for protein hydrolysates, e. g. "hydrolyzed wheat gluten," and "hydrolyzed soy protein."[7] Failure to list an ingredient on the food label, particularly an allergen, has resulted in product recalls. A recent review of FDA food recall actions for undeclared allergens such as peanuts, egg, or milk revealed an increase in recalls during the last decade. Recall activity increased from an average of 35 per year at the beginning of the last decade to an average of 90 per year during the last four years of the same decade (Figure 1).

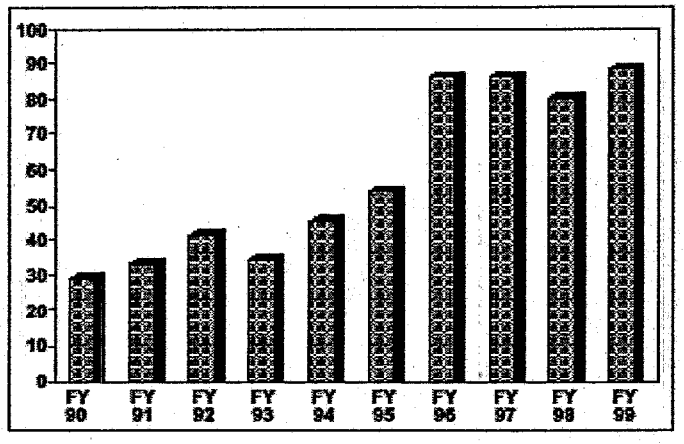


Figure 1. FDA food allergen recalls.

Additionally, FDA has received a number of reports of consumers who experienced adverse reactions following exposure to an allergenic substance in foods. Many of these exposures occurred because the presence of the allergenic substance in the food was not declared on the food label. This public health concern has prompted FDA

to develop an initiative on food allergen awareness.

In the spirit of the 1990 Nutrition Labeling and Education Act (NLEA), FDA's activities during the past 10 years have encouraged consumers to read the product label. While it is understood that an added ingredient must be declared in the ingredient statement, food manufacturers must pay particular attention to instances in which inadvertent introduction of allergens can potentially occur because of the firm's production practices; for example, rework addition, product carryover due to use of common equipment, production scheduling or allergenic product above exposed product lines.

In 1996, FDA issued a notice to the food industry alerting manufacturers and trade associations, requesting assistance in addressing the major public health problem of undeclared allergens in food.[8,9] FDA commented on current labeling requirements, voluntary labeling practices used by industry and various options such as additional rulemaking to alert consumers to the presence of allergens. In particular, the FDA noted the importance of declaring allergens even when present in very low amounts.

COLLECTIVE NAMING AND INCIDENTAL INGREDIENTS

The 1996 notice describing FDA's policy for food allergens outlined "exemptions" under the law for the labeling of ingredients, including food allergens on food packaging, and noted the use of precautionary statements such as "may contain" on food ingredient labeling. The "exemptions" are of two types: One focuses on collective naming of spices, flavors and colors, and the other on declaration of incidental additives such as processing aids.[10,11]

The first exemption refers to collective naming of flavors, certain colors (color additives exempt from certification in 21 *CFR* Part 73) and spices. Although these terms may be used on the food label, they are not completely descriptive. Food labels with collectively named additives may confuse individuals who wish to avoid allergenic substances, particularly when the allergenic substance is not clearly labeled. On several occasions, the FDA has clarified publicly that the FD&C Act allows spices, flavors, and colors to be declared collectively without naming each one. In some instances, these ingredients contain subcomponents that are allergens. Therefore, FDA recommends that processors declare allergenic ingredients in a spice or in a flavor. This might be accomplished by either declaring the allergenic ingredient by its common or usual name in the ingredient list as a separate ingredient or parenthetically following the term spice, flavor or color, or as a separate declaration immediately below the list of ingredients indicating the presence of the allergen. In addition, for some food labeling decisions, it is also clearly advantageous to the allergic consumer for the manufacturer to voluntarily declare any allergenic source from which an ingredient may be derived, such as soy, milk and eggs.

The second "exemption," incidental additives, refers to food substances that are exempt from labeling on an ingredient statement because they are used at or find

their way into food at insignificant levels and do not have any technical or functional effect in that food. In this case, each individual food firm makes an assessment of the food ingredients that may be introduced during food processing into their final food product and then determines the ingredient label. This can lead to errors in judgment by the food industry or others involved in food handling as to what ingredients should be declared on the food label. While FDA believes that every food firm makes a sincere effort to label the ingredients in their food products completely, it is also clear that firms do miss including allergenic ingredients on their food labels. This happens at times because subtle changes in food processing aids, such as filtering substances, may introduce allergenic components into the manufactured food and a company may simply not realize the addition of such an allergen to the final food product. The agency stated in its 1996 notice that ingredients that are food allergens do not meet the requirements for incidental additives and therefore are not exempt from ingredient declaration.[8,9] When these labeling errors are found by consumers or the food industry, the food label is usually corrected. At times, these errors also result in a recall of a company's products if they reach the marketplace.

PRECAUTIONARY LABELING STATEMENTS

The 1996 notice also addressed the use of precautionary labeling statements.[8,9] Statements such as "may contain peanuts" or "made on shared equipment" are voluntarily placed on food packaging labels by food manufacturers. These statements tend to express the manufacturers' concern that their food products could possibly contain other food ingredients not listed on the food label in the final food products. It is not clear whether the "may contain (ingredient)" is or is not present in this particular food package. The agency is gathering data on the extent of use of "may contain (ingredient)" and other precautionary labeling statements and intends to address their use in the future.

FOOD ALLERGEN INITIATIVES AND POLICY DEVELOPMENT

Beginning in 2000, CFSAN made increasing consumer and industry awareness to the presence of allergens in foods a high priority. In meeting the 2000 goal of increased awareness, CFSAN representatives held meetings at 14 locations in which they made presentations on allergen risks and labeling requirements.[12] CFSAN increased allergen awareness for those groups who provide food products to the public, as well for parents who may not be familiar with the challenges of caring for children who have a food sensitivity. These productive exchanges provided FDA with an opportunity to gather information for helpful consumer messages from individuals who, personally, or through their children, experienced allergic responses. For example, consumers suggested the use of certain terms to call attention to the presence of an allergen, i. e. use "milk" in the ingredient statement, if the formulation contains caseinate, or "egg" if the food contains albumin. The agency also sought to gain insight into industry allergen management practices and control methods. As part of the 2000 effort, FDA and state health departments began working cooperatively to establish uniform inspection procedures for food allergens.

Continuing these efforts with the 2001 CFSAN priorities, CFSAN plans to proceed with consumer and industry education efforts and to develop a strategy for clearer labeling of food allergens on the food label. Priorities include publishing a draft Compliance Policy Guide on manufacturing and labeling practices, issuing a field allergen inspection guide and providing training for FDA field offices. While emphasis is on the eight food allergens, FDA plans to publish a proposed rule to require declaration of carmine/cochineal extract on product labels.

OTHER RESEARCH ACTIVITIES

Survey. A national assessment of the extent of food allergenicity would be helpful to clarify who and to what extent consumers experience allergic reactions to food. The agency is studying ways to accomplish this survey and is seeking suggestions from those who are interested. One approach that is being considered is to use eight or nine regions of the country to determine, through hospital emergency room discharge codes, how many people have food allergen problems and anaphylaxis during the course of a year and how much of this anaphylaxis is caused by food. Investigating hospital discharge codes has been discussed in medical literature, but these studies have involved only isolated parts of the nation.[13]

Food Allergen Test Kits. Detecting the allergenic protein components of the eight major allergenic foods is the subject of much research and development. The developers of tests that can detect minute levels of these proteins have to produce antibodies for these proteins from animal sources. Once an antibody is isolated, barriers such as cross-reactivity to substances other than the desired proteins have to be addressed. Results must be reproducible and kits must be effective to detect these proteins in different foods.

A number of test kits are manufactured in this country for commercial use. Although there is not a test kit for each allergen in the food supply, kits are available for peanut, milk and egg protein. Other test kits for allergenic proteins are under development. The FDA is participating with the National Food Processors Association (NFPA) in establishing a peanut protein standard. A peanut flour standard is being developed that will be used to establish a common relationship or scale for the peanut protein test kits currently on the market. Although plans include standard development for other allergenic proteins, much work is needed to develop test kits and common standards for these proteins.

Food Allergen Thresholds. As mentioned above, quantitative food allergen thresholds are currently unknown. Although available data suggest that it is not possible to determine the amount of allergenic protein necessary to elicit an allergic reaction, discussions in public forums offer the hope that future research will determine a safe level for undeclared allergens in food.[14] FDA welcomes receiving any human data that might be available to help determine possible limits for the effects of allergenic proteins in sensitive populations.

OTHER INITIATIVES

Importantly, FDA recognizes the efforts of the food industry in addressing the presence of food allergens. For example, major industry representatives are supporting CFSAN priorities and have signaled development of a voluntary allergen labeling program.[15] Industry's senior management has made a commitment to managing allergens by training employees on allergens and plant-specific control procedures, evaluating rework procedures, working with ingredient suppliers to identify and label all allergenic ingredients in their products, requiring documentation of equipment cleaning and sharing best allergen practices with other corporations.

Information sharing among interested parties will go a long way to address the public health problem of food allergens. CFSAN anticipates that in 2001 public exchanges will continue through workshops as well as comments received on any guidance that issues. We look forward to constructive activities.

By Kenneth J. Falci, Ph.D., Kathy L. Gombas and Elisa L. Elliot, Ph.D.
Series Editor: Catherine "Kitty" Bailey, M.Ed.

***Kenneth J. Falci, Ph.D.**, is the Director of the Office of Scientific Analysis and Support, CFSAN, FDA. His office oversees development of economic impact analyses for food and cosmetic regulations, the conduct of consumer attitude studies including diet and disease, biotechnology and infant feeding practices. His office also provides epidemiological reviews for microorganism risk assessment, acute health hazard evaluations and estimates for the burden of foodborne illness. Post-market surveillance and adverse reactions to food products are also reported to his office.*

***Kathy L. Gombas** is the Deputy Director of the Division of HACCP Programs, CFSAN, FDA. Her division provides technical expertise and leadership in areas of food safety programs and HACCP to support the development of agency policies, regulations, standards and training.*

***Elisa L. Elliot, Ph.D.**, is a microbiologist in the Division of HACCP Programs, CFSAN, FDA, with lead responsibility for the food safety portion of the U. S. DHHS Healthy People 2010 initiative. She began her 11-year career with FDA as a researcher developing methods for* Vibrio *species.*

REFERENCES

1. U.S. FDA. 2001 CFSAN Program Priorities, p. 28. January 9, 2001.

2. Information on FDA's activities and general information on allergens may be accessed at www.cfsan.fda.gov/~dms/wh-alrgy.html. The Food Allergy and Anaphylaxis Network provides valuable information to consumers at

www.foodallergy.org.

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5. Hefle, S.L., et al. Allergenic foods. *Crit. Rev. Food Sci. Nutr.* (36) 5, pp. 69-89. 1996.

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8. U.S. FDA. Notice to Manufacturers. June 10, 1996. www.cfsan.fda.gov/~lrd/allerg7.html.

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10. Federal Food, Drug, and Cosmetic Act. Section 403 (i).

11. *Code of Federal Regulations*. 21 CFR 101.100 (3).

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