



# News Release

CALIFORNIA DEPARTMENT OF HEALTH SERVICES

NUMBER: 69-96  
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DATE: November 20, 1996  
CONTACT: Lynda Frost  
or Scott Lewis  
916/657-3064

## WARNING LABEL NOW REQUIRED ON CERTAIN HERB-CONTAINING FOOD PRODUCTS

SACRAMENTO--State Health Director Kim Belshé today announced that a new regulation will take effect on January 1, 1997 requiring that a label be placed on food products sold in California that contain herbal ingredients which can have laxative effects. Food products covered by the new regulation are primarily herb teas often labeled to suggest they assist with weight loss and dietary supplements often labeled for colon cleansing or toning.

Herbs covered by the regulation include senna (often listed as *Cassia angustifolia*), aloe, buckthorn, cascara, frangula and rhubarb root. Any food product containing any of these herbs must have the following statement conspicuously displayed on its label:

NOTICE: This product contains (name of ingredient and common name if different). Read and follow directions carefully. Do not use if you have or develop diarrhea, loose stools or abdominal pain. Consult your physician if you have frequent diarrhea. If you are pregnant, nursing, taking medication, or have a medical condition, consult your physician before using this product.

The California Department of Health Services (DHS) adopted the regulation after receiving complaints from consumers that some first-time users of teas containing senna developed abdominal pain and diarrhea and some regular users developed significant health problems from low levels of potassium in their blood.

DHS laboratory staff measured the quantity of chemicals with laxative effects in seven brands of senna-containing tea that are sold as food or dietary supplements. All seven brands, when prepared according to label directions, contained quantities of those chemicals comparable to those found in over-the-counter laxative products which already carry a warning label.

Frequent use of products containing chemicals with laxative effects can cause low blood potassium and loss of normal bowel function. The new label will help assure that consumers have the information they need to safely use products containing these chemicals. DHS worked with the industry representatives to develop the label statement and some began using it before it will become mandatory.

Foods such as raisins, prunes, and bran, which may have laxative effects on some people, do not contain these same chemicals and therefore do not have adverse health implications.

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During its investigation, DHS determined that some consumers mistakenly believe that the diarrhea the teas can produce reduced the body's absorption of food calories. Diarrhea does not reduce the body's absorption of calories. The apparent weight loss comes from increased loss of water caused by the secretion of water and important minerals into the waste stream.

If consumers are experiencing undesirable reactions from drinking teas or using dietary supplements that contain senna (often listed as *Cassia angustifolia*), aloe, buckthorn, cascara, frangula and rhubarb root, DHS recommends they stop using them and contact a physician.

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**ACTION:** Notice of Emergency Rulemaking

**SUBJECT:** Label Requirements for Foods (R-38-95E)

**PUBLIC PROCEEDINGS:** Notice is hereby given that the California Department of Health Services will conduct written public proceedings during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions relevant to the action described in this notice. Any written statements, arguments or contentions must be received by the Office of Regulations, Department of Health Services, 714 P Street, Room 1000, P.O. Box 942732, Sacramento, CA 94234-7320, by 5:00 p.m. on December 16, 1996, which is hereby designated as the close of the written comment period. It is requested but not required that written statements, arguments or contentions be submitted in triplicate.

**CONTACT:** Inquiries concerning the action described in this notice may be directed to Charles E. Smith of the Office of Regulations at (916) 657-0730. In any such inquiries, please identify the action by using the Department regulation control number R-38-95E.

Persons wishing to use the California Relay Service may do so at no cost. The telephone numbers for accessing this service are: 1-800-735-2929, if you have a TDD; or 1-800-735-2922, if you do not have a TDD.

**INFORMATIVE DIGEST:** California Health and Safety Code, Section 110065 authorizes the Department of Health Services to adopt regulations including adoption of additional food labeling regulations under authority of Section 110100(b). For additional food labeling regulations, the Department must seek comments from consumer groups and representatives of the food industry affected by the emergency regulations prior to adoption. The emergency regulations, California Code of Regulations, Title 17, Article 1. Definitions, Section 10200. "Dietary Supplement" and Article 3. Section 10750. "Label Requirements for Foods and Dietary Supplements," define dietary supplement and specify the label statement and the format of that statement required for the lawful sale of foods and dietary supplements containing aloe, buckthorn, cascara, frangula, rhubarb root, and/or senna (substances that can have stimulant laxative effects). The California Health and Safety Code states that 1) labeling of foods, drugs, and cosmetics is misleading if it fails to reveal material facts or consequences of customary use, Section 110290; 2) these products are misbranded if their labeling is false or misleading in any particular, Section 110660 - food, Section 111330 - drug, Section 111730 - cosmetic; and 3) these products are misbranded if a required label statement

is not conspicuously displayed such that it is likely to be read and understood, Section 110705 - food, 111345 - drug, 111745 - cosmetic. It is unlawful for any person to sell or offer for sale these products if they are misbranded, Sections 110760, 110765, 110770 - food; Sections 111440, 111445, 111450 - drug; and Sections 111765, 111770, 111775 - cosmetic.

Plain English Policy Statement Overview: The objectives of the emergency regulations are to 1) provide for lawful sale of foods and dietary supplements containing aloe, buckthorn, cascara, frangula, rhubarb root, and/or senna, and 2) inform consumers when to avoid using these products because of potential health risks. The emergency regulations primarily affect certain herbal teas and dietary supplements of capsules and tablets. Information will be provided by a notice on the label displayed in a specified format that reveals material facts about these foods. The notice will instruct consumers to read and follow directions carefully and will inform consumers when not to use the product and when to consult with a doctor before using the product.

AUTHORITY: Sections 100275, 110065, 110290, 110660, 110705 and 110765, Health and Safety Code.

REFERENCE: Section 110175, Health and Safety Code.

FISCAL IMPACT ESTIMATE:

- A. Fiscal Effect on Local Government: No fiscal impact exists.
- B. Fiscal Effect on State Government: No costs associated with enforcement.
- C. Fiscal Effect on Federal Funding of State Programs: No fiscal impact exists.
- D. Fiscal Effect on Private Persons or Businesses Directly Affected: For businesses directly affected, an estimated one-time cost of relabeling would be \$850.00 per product.

DETERMINATIONS: The Department has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

The Department has determined that the emergency regulation would not have a significant adverse economic impact on businesses, including the ability of California businesses to compete with businesses in other states. Three firms with national distributions (Body Breakthrough Inc., Deer Park, New York; General Nutrition Corporation (GNC), Pittsburgh, Pennsylvania; and Hobe Laboratories, Phoenix, Arizona) have informed the Department that

they have ordered new labels bearing the language specified in the emergency regulations. Current labels of Laci Le Beau, Super Dieter's Tea bear the label statement specified in the emergency regulations. In addition, a GNC representative informed the Department that GNC will begin requiring this labeling on all affected products distributed in their stores.

The Department has determined that the regulations would not significantly affect the following:

(1) The creation or elimination of jobs within the State of California.

(2) The creation of new businesses or the elimination of existing businesses within the State of California.

(3) The expansion of businesses currently doing business within the State of California.

The Department has shared information on the emergency regulation with representatives of 1) small and large business, 2) trade associations, 3) FDA, 4) other state health departments, 5) the Association of Food and Drug Officials, and 6) consumer groups. None of these representatives have expressed concern that these emergency regulations would have an adverse economic impact on California firms or firms doing business in California.

The Department has determined that the regulations would affect small business.

The express terms of the emergency action written in plain English is available from the Office of Regulations at the address noted above.

**AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS:** The Department has prepared and has available for public review an initial statement of reasons for the emergency regulations, all the information upon which the emergency regulations are based, and the text of the emergency regulations. A copy of the initial statement of reasons and a copy of the text of the emergency regulations are available upon request by writing to the Office of Regulations at the address noted above, which address will also be the location of public records, including reports, documentation, and other material related to the emergency regulations.

**AVAILABILITY OF CHANGED OR MODIFIED TEXT:** The full text of any regulation which is changed or modified from the express terms of the emergency action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

ADDITIONAL STATEMENTS AND COMMENTS: In accordance with Government Code Section 11346.5(a)(12) the Department must determine that no alternative considered by the Department would be more effective in carrying out the purpose for which the action was taken or would be as effective and less burdensome to affected private persons than the emergency action.

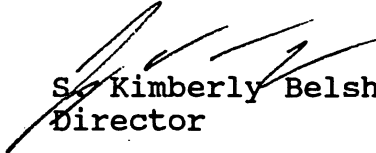
Any interested person or his or her duly authorized representative may request, no later than 15 days prior to the close of the written comment period, a public hearing pursuant to Government Code Section 11346.8.

Reasonable accommodation or sign language interpreting services at a public hearing will be provided upon request. Such request should be made no later than 15 days prior to the close of the written comment period.

DEPARTMENT OF HEALTH SERVICES

R-38-95E

Dated: October 1, 1996

  
S. Kimberly Belshé  
Director

## FINDING OF EMERGENCY

Emergency action is required for the immediate preservation of the public health and safety. Foods and dietary supplements containing substances that can have stimulant laxative effects are causing illnesses, permanent injury, and possibly death in Californians. These products are primarily herb teas often labeled to suggest weight loss (dieter's, slim, trim) and dietary supplements often labeled for colon cleansing or toning. The Department's Food and Drug Branch (FDB) has learned of 67 illnesses in first time and regular consumers of "dieter's" teas and up to ten deaths in regular consumers. While it has not been proven that these foods caused the illnesses and deaths, use and abuse of stimulant laxatives can cause illnesses and deaths similar to those experienced by individuals consuming these foods. Abdominal pain and diarrhea can occur in first time consumers, but the risk of serious illness (e.g., electrolyte disturbances, particularly hypokalemia, leading to muscle weakness, permanent kidney damage and life-threatening cardiac arrhythmias) appears to arise only after frequent episodes of diarrhea. At least two of the ten deaths resulted from cardiac arrhythmias during episodes of hypokalemia.

Even though individuals may associate consuming these products with laxative effects, they do not necessarily understand that these products may be causing other health problems since the products are: 1) sold in health food stores and conventional grocery and drug stores; 2) bear little or no information about health risks; and 3) often claim to be caffeine-free and made with all natural ingredients (claims consumers associate with safety). Some consumers use "dieter's" teas and "colon cleanser" as laxatives, in preference to over-the-counter laxative drugs, believing that these products are safer since they do not bear health risk information.

Without informative labeling, consumers continue to consume these products when ill, placing themselves at risk of permanent injury or life-threatening complications. FDB found that many people do not understand that severe diarrhea lasting one or two weeks, or several episodes of diarrhea a day for months to years can jeopardize their health. Therefore, the emergency regulation requires that consumers be informed: 1) not to use these products if they have or develop diarrhea, loose stools, or abdominal pain; and 2) to consult a physician if they have frequent episodes of diarrhea. With informative labeling, consumers will know how to safely use these foods.

Consumer protection requires emergency action.

**INFORMATIVE DIGEST:** California Health and Safety Code, Section 11065 authorizes the Department of Health Services to adopt regulations necessary for the enforcement of

this part including adoption of additional food labeling regulations under authority of Section 110100(b). For additional food labeling regulations, the Department must seek comments from consumer groups and representatives of the food industry affected by the proposed regulation prior to its adoption. The emergency regulations, California Code of Regulations, Title 17, Article 1. Definitions, Section 10200. "Dietary Supplement" and Article 3. Section 10750. Label Requirements for Foods and Dietary Supplements, define dietary supplement and specify the label statement and the format of that statement required for the lawful sale of foods and dietary supplements containing aloe, buckthorn, cascara, frangula, rhubarb root, and/or senna (substances that can have stimulant laxative effects). The California Health and Safety Code states that 1) labeling of foods, drugs, and cosmetics is misleading if it fails to reveal material facts or consequences of customary use, Section 110290; 2) these products are misbranded if their labeling is false or misleading in any particular; Section 110660 — food, Section 111330 — drug, Section 111730 — cosmetic; and 3) these products are misbranded if a required label statement is not conspicuously displayed such that it is likely to be read and understood, Section 110705 — food, 111345 — drug, 111745 — cosmetic. It is unlawful for any person to sell or offer for sale these products if they are misbranded, Sections 110760, 110765, 110770 — food; Sections 111440, 111445, 111450 — drug; and Sections 111765, 111770, 111775 — cosmetic.

**Plain English Policy Statement Overview:** The objectives of the emergency regulations are to 1) provide for lawful sale of foods and dietary supplements containing aloe, buckthorn, cascara, frangula, rhubarb root, and/or senna, and 2) inform consumers when to avoid using these products because of potential health risks. The emergency regulations primarily affect certain herbal teas and dietary supplements of capsules and tablets. Information will be provided by a notice on the label displayed in a specified format that reveals material facts about these foods. The notice will instruct consumers to read and follow directions carefully and will inform consumers when not to use the product and when to consult with a doctor before using the product.

**AUTHORITY:** Sections 100275, 110065, 110290, 110660, 110705 and 110765, Health and Safety Code.

**REFERENCE:** Section 110175, Health and Safety Code.

#### **FISCAL IMPACT ESTIMATE:**

- A. Fiscal Effect on Local Government: No fiscal impact exists.
- B. Fiscal Effect on State Government: No costs associated with enforcement.
- C. Fiscal Effect on Federal Funding of State Programs: No fiscal impact exists.



- D. **Fiscal Effect on Private Persons or Businesses Directly Affected:** For businesses directly affected, an estimated one-time cost of relabeling would be \$850.00 per product.

**DETERMINATIONS:** The Department has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

The Department has determined that the emergency regulation would not have a significant adverse economic impact on businesses, including the ability of California businesses to compete with businesses in other states. Three firms with national distributions (Body Breakthrough Inc., Deer Park, New York; General Nutrition Corporation (GNC), Pittsburgh, Pennsylvania; and Hobe Laboratories, Phoenix, Arizona) have informed the Department that they have ordered new labels bearing the language specified in the emergency regulations. Current labels of Laci Le Beau, Super Dieter's Tea bear the label statement specified in the emergency regulations. In addition, a GNC representative informed the Department that GNC will begin requiring this labeling on all affected products distributed in their stores.

The Department has determined that the regulations would not significantly affect the following:

- (1) The creation or elimination of jobs within the State of California.
- (2) The creation of new businesses or the elimination of existing businesses within the State of California.
- (3) The expansion of businesses currently doing business within the State of California.

The Department has shared information on the emergency regulation with representatives of 1) small and large business, 2) trade associations, 3) FDA, 4) other state health departments, 5) the Association of Food and Drug Officials, and 6) consumer groups. None of these representatives have expressed concern that these emergency regulations would have an adverse economic impact on California firms or firms doing business in California.

The Department has determined that the regulations would affect small business.

The express terms of the emergency action written in plain English is available from the Office of Regulations at the address noted above.

## INITIAL STATEMENT OF REASONS.

Aloe, buckthorn, cascara, frangula, rhubarb root (not stalks), and senna are substances that contain stimulant laxative chemicals called anthraquinones. Foods and dietary supplements containing these substances are currently being marketed in California. Federal and state laws specifically authorize the sale of foods containing aloe, cascara, rhubarb root, and senna as food additives but set no specific upper limits on the amounts that can be used.<sup>1,2</sup> Federal and state laws prohibit the sale of foods, drugs, and cosmetics if their labels fail to reveal material facts or consequences of customary use<sup>3,4</sup> and prohibits their sale if a required label statement is not conspicuously displayed such that it is likely to be read and understood by individuals purchasing or using the products.<sup>5,6</sup> State law authorizes the Department of

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<sup>1</sup> Title 21 *Code of Federal Regulations*, Section 172.510(a)

<sup>2</sup> *California Health and Safety Code*, Section 110085.

<sup>3</sup> *Federal Food, Drug, and Cosmetic Act*, 21 U.S.C., Section 321(n) (misleading), 331 (unlawful sale), and [343(a)(1) (food), 352(a) (drug), 362(a) (cosmetic) (misbranding)].

<sup>4</sup> *California Health and Safety Code*, Sections 110290 (misleading), [food — 110760, 110765, and 110770 (unlawful sale); 110660 (misbranded)], [drug — 111440, 111445, and 111450 (unlawful sale); 111330 (misbranded)] [cosmetic — 111765, 111770, and 111775 (unlawful sale); 111730 (misbranded)].

<sup>5</sup> *Federal Food, Drug, and Cosmetic Act*, 21 U.S.C., Section 343(f) (food), 352(c) (drug), 362(c) cosmetic).

<sup>6</sup> *California Health and Safety Code*, Section 110705 (food), 111345 (drug), 111745 (cosmetic).

Health Services (Department) to adopt any necessary regulations, including additional food labeling regulations, provided that the Department seeks comments from consumer groups and representatives of the food industry affected by the proposed labeling regulation prior to its adoption.<sup>7</sup>

The Department's Food and Drug Branch (FDB) has learned of 67 illnesses in first-time and regular consumers of "dieter's" teas containing substances that can have stimulant laxative effects and up to ten deaths in regular consumers. While it has not been proven that the teas caused the illnesses and deaths, use and abuse of stimulant laxatives can cause illnesses and deaths similar to those experienced by consumers of these teas. First-time consumers of "dieter's" tea report abdominal pain and diarrhea, but the risk of serious illness (e.g., electrolyte disturbances leading to muscle weakness, permanent kidney damage, and life-threatening cardiac arrhythmias) appears to arise only after frequent episodes of diarrhea.

The minimum quantity of stimulant laxative chemicals that causes diarrhea is unknown and the quantity of these chemicals in products covered by this emergency regulation varies widely. Accordingly, the Department has adopted this emergency regulation to require manufacturers and packagers of foods and dietary supplements containing any amount of aloe, buckthorn, cascara, frangula, rhubarb root and/or senna to provide a statement on the

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<sup>7</sup> California Health and Safety Code, Section 110065 and 110100 (b).

label that informs consumers how to safely use these products. This emergency regulation also specifies the attributes of this label statement, including placement in a box and minimum type size, to assure that it will be read and understood by individuals purchasing and consuming these products. Products covered by the emergency regulation are primarily herb teas often labeled to suggest weight loss (dieter's, slim, trim) and dietary supplements often labeled for colon cleansing or toning. The boxed notice below shows an example of a label statement that satisfies the requirements of the emergency regulation.

NOTICE: This product contains (name of substance(s) and common name if different). Read and follow directions carefully. <u>Do not use if you have or develop diarrhea, loose stools, or abdominal pain.</u> Consult your physician if you have frequent diarrhea. If you are pregnant, nursing, taking medication, or have a medical condition, consult your physician before using this product.
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BACKGROUND: In 1987, FDB began receiving sporadic complaints of gastrointestinal disturbances from consumers of "dieter's" teas containing senna. Between 1992 and 1994, FDB learned of four deaths (one in California) in otherwise healthy young women who reportedly drank senna-containing teas for months to years before they died. Upon learning of the first two deaths, FDB asked the Department's Environmental Health Investigations Branch (EHIB) for assistance in evaluating these deaths. EHIB's evaluation concluded that it would be difficult to determine that the teas caused these deaths, but the teas could

exacerbate low blood potassium (hypokalemia), a potentially life-threatening condition.<sup>8</sup>

After learning of two additional deaths, FDB asked EHIB to evaluate these deaths but their conclusions did not change. Two of the four deaths evaluated by EHIB resulted from cardiac arrhythmias during episodes of hypokalemia.

These four deaths prompted a wrongful death lawsuit in December 1994 against several firms including a California manufacturer of "dieter's" teas.<sup>9</sup> Following media coverage of this lawsuit, FDB received additional illness complaints and six additional reports of deaths, four in California and one in April 1996.

Table 1 summarizes 67 illness complaints, not including deaths, received by FDB either directly or through the U. S. Food and Drug Administration (FDA). Table 2 summarizes detailed information on preparation methods and quantity, frequency and duration of tea consumption for complaints received by FDB. This information is not available for complaints received through FDA. Reports of problems experienced by first-time consumers generally include unexpected abdominal cramps and diarrhea, at times severe and lasting

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<sup>8</sup> July 7, 1995 memo: Evaluation of Laci LeBeau Super Dieter's Tea, pages 1-2, from Richard Kreutzer, M.D., Acting Chief, Environmental Health Investigations Branch, to Stuart E. Richardson, Jr., M.P.H., Chief, Food and Drug Branch, following evaluation of two deaths.

<sup>9</sup> Robert Christopher Grell, et al. v. Laci Le Beau, et al. San Francisco County Superior Court Case No. 965787.

several days. Reports of problems experienced by repeat consumers include persistent abdominal pains, muscle weakness, electrolyte disturbances, and impaired bowel function.

Even though individuals may associate drinking these teas with laxative effects, they do not necessarily understand that the teas may be causing other health problems since the teas are: 1) sold in health food stores and conventional grocery and drug stores; 2) bear little or no information about health risks; and 3) often claim to be caffeine-free and made with all natural ingredients (claims consumers associate with safety). Some consumers use "dieter's" teas as laxatives, in preference to over-the-counter (OTC) laxative drugs, believing that the teas are safer since they do not bear health risk information.

Most foodborne illnesses are never reported, so it is likely that the complaints listed in Tables 1 and 2 represent only a fraction of the people who have become ill. Using food-borne illnesses caused by *Salmonella* infections as an example, only one to five percent of the people getting sick report their illnesses.<sup>10</sup> People suffering from *Salmonella* infections may think they have the flu instead of a food-borne illness, may not know who to inform, or may feel that their complaints are unimportant. After experiencing diarrhea, loose stools, and/or abdominal pain (reactions to stimulant laxative chemicals) from

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<sup>10</sup> Chalker, R.B. and M.J. Blaser, 1988, A review of human salmonellosis: III. Magnitude of *Salmonella* Infection in the United States. *Review of Infectious Diseases* 10:111-124.

consuming "dieter's" teas or colon cleansers, consumers may assume the products were supposed to produce these effects. They may either stop using the products without reporting a complaint or continue to use them despite (or because of) the laxative effects, without understanding the potential health risks.

Table 3 shows the Department's measurements of the quantities of stimulant laxative chemicals (sennosides A and B) in nine brands of senna-containing teas. Seven brands are sold as foods (including several flavors of some brands) and two brands are sold as OTC stimulant laxative drugs. OTC stimulant laxative drugs containing senna are considered safe and effective for the treatment of occasional constipation provided that they contain between 12 to 50 milligrams (mg) sennosides A and B to be taken once or twice a day.<sup>11</sup> The Department tested teas containing senna because they were the types of products most complained about and because results could be compared with the amounts of these chemicals found in OTC stimulant laxative drugs. The two brands of tea sold as OTC stimulant laxative drugs, when prepared according to label directions, contained quantities of sennosides A and B below the levels specified for these drugs. All seven brands of tea sold as foods, when prepared according to label directions (or sometimes for shorter times than

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<sup>11</sup> 51 *Federal Register* 35316-7, October 1, 1986, Food and Drug Administration, Laxative Drug Products for Over-the-Counter Human Use - Tentative Final Monograph.

directed on the label), contained quantities of sennosides A and B in the range specified for OTC stimulant laxative drugs.

Even though teas and dietary supplements may contain levels of sennosides A and B in the range of OTC stimulant laxative drugs, they can be sold as foods if their intended use is for flavor, nutrition, or aroma (food uses) and not to diagnose, cure, mitigate, treat, or prevent diseases (drug uses). The use of aloe, cascara, rhubarb root and/or senna as flavorings in food is limited to the minimum quantity required to produce the intended physical or technical effect.<sup>12</sup> Federal law limits the use of aloe, buckthorn, cascara, frangula, rhubarb root and/or senna in dietary supplements to levels that do not present a significant or unreasonable risk of illness.<sup>13</sup> But there are no specific upper limits for either use.

The most serious health risks from foods and dietary supplements containing aloe, buckthorn, cascara, frangula, rhubarb root and/or senna (substances that can have stimulant laxative effects) are electrolyte disturbances, particularly hypokalemia, from frequent episodes of diarrhea.<sup>14,15</sup> The potential consequences of hypokalemia include muscle weakness,

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<sup>12</sup> Title 21, *Code of Federal Regulations*, Section 172.510(a).

<sup>13</sup> *Federal Food, Drug, and Cosmetic Act*, 21 U.S.C., Section 342(f)(1)(A)

<sup>14</sup> Stein, J. H. 1988, Hypokalemia common and uncommon causes. *Hospital Practice (Office Edition)* 23(3A):55-70.

<sup>15</sup> Personal communication: James Wirth, M.D., Ph.D., Director, Eating Disorders Program, Johns Hopkins Hospital



permanent kidney damage, and life-threatening cardiac arrhythmias.<sup>16</sup> Conversations with consumers experiencing diarrhea during the time they were drinking "dieter's" teas showed that these individuals did not understand that two to three episodes of diarrhea a day for months to years or severe diarrhea lasting only a week can jeopardize their health.

Therefore, the emergency regulation requires that consumers be informed: 1) not to use these foods or dietary supplements if they have or develop diarrhea, loose stools, or abdominal pain; and 2) to consult a physician if they have frequent episodes of diarrhea.

At sufficiently low levels, aloe, buckthorn, cascara, frangula, rhubarb root and/or senna will not cause diarrhea. However, these levels have not been determined for any substance, will be different for each substance, and will change depending on individual sensitivity, the effects of other foods or drugs, concurrent illnesses, and other factors. Therefore, the emergency regulation requires the label statement for foods and dietary supplements containing any amount of these substances.

Daily ingestion of excessive quantities of stimulant laxative chemicals over many years has been found to damage nerves in the colon.<sup>17,18</sup> This observation raises the possibility of

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<sup>16</sup> *Scientific American Medicine*, 10, II, 19, January 1993.

<sup>17</sup> Rieken, E. -O. et al. 1990, The effect of an anthraquinone laxative on colonic nerve tissue: A controlled trial in constipated women. *Zeitschrift für Gastroenterologie* 28:660-664.

impaired bowel function in long-term consumers of foods and dietary supplements containing stimulant laxative chemicals. However, FDB is not aware of any data showing that long-term consumption of stimulant laxative chemicals in teas or dietary supplements (at levels that do not produce diarrhea, loose stools, or abdominal pain) creates a risk of impaired bowel function.

The Department shared its laboratory data, illness reports, and toxicity assessment with FDA, industry representatives, and representatives of consumer groups. During meetings on May 15 and July 10, 1995, Department and FDA Pacific Region staff and industry representatives met to discuss the potential health risks from these products and corrective measures that could be taken. On June 7 and 8, 1995, FDB made a presentation to a Special Working Group convened by FDA to address whether foods containing substances that can have stimulant laxative effects should bear informative labeling. The Special Working Group concluded that these foods should bear informative labeling and suggested such labeling.<sup>19</sup> At a meeting on June 8 and 9, 1995, FDA's Food Advisory Committee approved the actions of the Special Working Group. The Food Advisory Committee functions as an expert advisor to FDA. At a meeting on August 7, 1995, Department and FDA Pacific Region

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<sup>18</sup> Reimann, J. F., H. Schmidt and W Zimmermann, 1980, The fine structure of colonic submucosal nerves in patients with chronic laxative abuse. *Scand. J. Gastroenterology* 15:761-80.

<sup>19</sup> June 19, 1995, FDA advisory committee endorses labels on laxative diet teas. *Food Chemical News*, 44-46.

staff and industry representatives reached consensus on the wording of the label statement that should be required. The label statement agreed to at the August 7, 1995 meeting is the label statement adopted in this emergency regulation. Some firms have already begun to include this statement on their products.

The following describes each provision of the emergency regulation and addresses comments received about the emergency regulation to date:

Article 1. "Definitions" is added to Title 17, California Code of Regulations, Division 1, Chapter 5, Subchapter 2, Group 1.

This provision was necessary to provide a location for the definition of dietary supplement.

Section 10200 defines "Dietary Supplement."

The products covered by the emergency regulation are foods and dietary supplements. The term "food" is already defined in California law. Section 10200 defines "dietary supplement" using several criteria related to the products intended use, form, ingredients, and labeling. It parallels the federal definition of the term recently

adopted in the Dietary Supplement Health and Education Act of 1994 (DSHEA),<sup>20</sup> except that cross-references to other laws are made to the corresponding California laws. Following the federal definition avoids confusion in the regulated industry which is already familiar with the federal requirements in DSHEA. It is much easier for businesses directly affected by the emergency regulation to understand the scope of the regulation, if the state and federal definitions of "dietary supplement" are similar.

Section 10750 (a) specifies the type of products required to bear the label notice (foods and dietary supplements) and that the label notice is required for products containing any amount of specific substances (listed in Table 10750 A).

This section provides that foods and dietary supplements containing any amount of substances listed in Table 10750 A (common name: aloe, buckthorn, cascara, frangula, rhubarb root, and senna) must comply with the emergency regulation. At sufficiently low levels these substances will not have stimulant laxative effects, but these levels are unknown. Industry representatives agreed with the provision to require the label statement on foods or dietary supplements containing any amount of the substances listed in Table 10750 A.

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<sup>20</sup> Dietary Supplement Health and Education Act (DSHEA), P.L. 103-417, section 3.

Section 10750 (a) (1) specifies the notice required on products with more than 12 square inches available for labeling.

This provision is necessary so that the labels of all foods and dietary supplements containing substances listed in Table 10750 A (aloe, buckthorn, cascara, frangula, rhubarb root and/or senna) provide uniform information necessary for consumers to use the products safely. Since the most serious health risks from these products are electrolyte disturbances, particularly hypokalemia, caused by frequent episodes of diarrhea, the label statement identifies diarrhea as the primary condition that consumers must watch for. Since diarrhea is an easily recognizable warning sign, informing consumers not to use these foods when diarrhea is present provides them with adequate protection. Information about use during pregnancy or nursing, while taking medication, or with a medical condition, is provided as appropriate guidance for consumers that may be more sensitive to products containing substances that can have stimulant laxative effects. This information appeared on some labels of "dieter's" teas prior to FDB's discussions with industry representatives.

The Center for Science in the Public Interest supports the Department's efforts and agrees with the language of the label statement required by the emergency regulation.

FDA supports the Department's efforts to establish this emergency regulation, with some comments.<sup>21</sup> FDA pointed out that the label statement might be improved if it informed users that: 1) the foods may act as laxatives; 2) laxative-induced diarrhea does not reduce absorption of food calories; and 3) long-term consumption of the product may result in impaired bowel function.

FDB considered including statements that the products can have stimulant laxative effects and that laxative-induced diarrhea does not reduce absorption of food calories but did not include them because many consumers regard laxation as a desirable effect. A statement that might encourage consumers to use these products as laxatives, (e.g., "may have stimulant laxative effects") would be inappropriate. Consumers needing a laxative should use properly labeled drug products. It would also be inappropriate to require food labels to feature general health messages (e.g., "diarrhea does not reduce absorption of food calories"). The purpose of this emergency regulation is to inform consumers how to safely use these products, not to correct misconceptions about the absorption of food calories. Too many label statements could diminish the impact of the most important message (i.e., to avoid diarrhea).

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<sup>21</sup> August 3, 1995 letter from I. Kaye Wachsmuth, Ph.D., Deputy Director for Programs, Center for Food Safety and Applied Nutrition, to Stuart E. Richardson, Jr., M.P.H., Chief, Food and Drug Branch.

FDB is not aware of any data which establish that long-term consumption of stimulant laxative chemicals in teas or dietary supplements (at levels that do not produce diarrhea, loose stools, or abdominal pain) creates a risk of impaired bowel function. So the label statement informs users not to use these products in amounts that cause laxation.

Section 10750 (a) (2) specifies that the label notice must be surrounded by a box and the minimum type size and characteristics of the notice.

These requirements assure that the label notice is readily recognized and easy to read. FDA's recent experience with the graphic requirements for the Nutrition Facts label and focus-group discussions of this label found that putting label statements in a boxed area draws consumers attention and helps consumers distinguish the boxed statement from other information on the label.<sup>22</sup> FDA's recent approval of Olestra as a fat substitute in savory snacks requires that foods containing Olestra bear a label statement with the same specifications for the surrounding box, type size and style specified in this emergency regulation.<sup>23</sup>

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<sup>22</sup> 61 *Federal Register* 3118 at 3162, January 30, 1996.

<sup>23</sup> 21 *Code of Federal Regulations*, Section 172.867 (e)(2) and (e)(3).

Section 10750 (a) (3) specifies that for products in packages with less 12 square inches available to bear labeling the complete notice required by paragraph (a) (1) in the format specified in (a) (2) must be provided with the product either as a package insert or on a tag attached to the package. This paragraph also specifies the notice required to appear on the label of these products.

This provision is necessary to accommodate the needs of persons subject to the emergency regulation who market their products in small packages. Twelve square inches were chosen as the cutoff to be consistent with federal requirements for nutrition labeling of foods in small packages that also provide a twelve square inches cutoff for full required labeling.<sup>24</sup>

Section 10750 (a) (4) specifies that the label notice must be surrounded by a box and the minimum type size and characteristics of the notice.

Accommodations for products in small packages provides for a six point minimum font size. A six point font can generally be read by most consumers providing there

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<sup>24</sup> Title 21, *Code of Federal Regulations*, Section 101.9(j)(13)(i).



is adequate contrast,<sup>25</sup> but is two points smaller than specified for the label on larger packages.

This provisions is necessary to assure that consumers have access to the complete label notice including information to read and follow directions carefully, to consult their physician if they have frequent diarrhea, and to consult their physician before using the product if they are pregnant, nursing, taking medication, or have a medical condition.

Section 10750 (b) provides an exemption for products containing a form of aloe (leaf gel) that does not contain anthraquinones and so does not have stimulant laxative effects. This provision is necessary to accommodate the sale of products that would otherwise be improperly subject to the emergency regulation's requirements.

Table 10750 A identifies the common and botanical names, and the plant parts, of substances whose presence requires the label notice. This provision is necessary to give adequate notice to persons subject to the emergency regulation as to the specific substances that are covered.

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<sup>25</sup> Label Readability Guidelines, Nonprescription Drug Manufacturers Association, JP1091-R7.5M.

The six substances covered by the emergency regulation (common names: aloe, buckthorn, cascara, frangula, rhubarb root, and senna) can have stimulant laxative effects because of the presence of chemicals known as anthraquinones (e.g., sennosides A and B). Although most people reporting adverse reactions consumed teas containing senna, all the substances covered by the emergency regulation have the potential to cause stimulant laxative effects and pose the same potential health risks to consumers (hypokalemia leading to muscle weakness, permanent kidney damage, and life-threatening cardiac arrhythmias).<sup>26</sup> A market survey conducted by FDB found herbal teas and dietary supplements that contain each of the six substances covered by the emergency regulation.

*Adverse Effects of Herbal Drugs*, referenced in footnote 25, describes the botany, chemistry, pharmacology and uses, and adverse reaction profiles of the six substances listed in the emergency regulation.<sup>27</sup> The list of common names, plant parts, and botanical names of the substances covered by the emergency regulation was finalized following discussion and agreement with two experts on herbal substances used in foods, Alvin B. Segelman, Ph.D, Vice President for Corporate Health Sciences,

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<sup>26</sup> *Adverse Effects of Herbal Drugs*, P.A.G.M. DeSmet (editor), Anthranoid Derivatives - General Discussion, Westendorf, J., 105-118, Springer-Verlag, 1993.

<sup>27</sup> *Adverse Effects of Herbal Drugs*, P.A.G.M. DeSmet (editor), Anthranoid Derivatives - Aloe Species, 119-123, Anthranoid Derivatives - Cassia Species, 125-128, Anthranoid Derivatives - Rhamnus Species, 129-131, and Anthranoid Derivatives - Rheum Species, 132-136. Westendorf, J., Springer-Verlag, 1993.

Nature's Sunshine Products and Michael McGuffin, President, American Herbal Products Association. The final list was provided to Samuel Page, Ph.D., Director of FDA's Division of Natural Products for comments and/or corrections. Dr. Page did not suggest any changes to this list.

The emergency regulation requires a label statement on foods and dietary supplements containing aloe, buckthorn, cascara, frangula, rhubarb root, and/or senna. This statement alerts consumers: 1) to read and follow directions carefully; 2) not to use the product if experiencing diarrhea, loose stools, or abdominal pain; 3) to consult a physician if experiencing frequent diarrhea; and 4) to consult a physician before using the product if pregnant, nursing, taking medication, or with a medical condition.

The emergency regulation is necessary to: 1) protect California consumers by informing them how to safely use these products; 2) prevent unlawful sale of these products; and 3) achieve uniform industry compliance.

The emergency regulation is the best method to achieve these goals. The information provided by a label statement on products covered by the emergency regulation is always available to prospective purchasers and users in the event of questions or unexpected reactions. Health alerts and press releases do not reach all prospective purchasers and their messages are quickly forgotten. Enforcement actions against individual firms for selling

misbranded products allows untargeted products to remain in the marketplace posing an ongoing risk to consumers and creating inequalities when consumers purchase unlabeled products believing they are safer. To do nothing or wait for FDA to adopt regulations continues to put consumers at risk from using these products in ways that can endanger their health.

The emergency regulation does not overlap or duplicate any state or federal statute or regulation. If FDA adopts regulations in this area, the Department intends to repeal this emergency regulation.

The Department is relying on the documents cited in the footnotes in adopting this emergency regulation.

The emergency regulation mandates no specific technologies or equipment.

The Department considered four alternatives to this emergency regulation:

1. Prohibit the sale of foods and dietary supplements containing aloe, buckthorn, cascara, frangula, rhubarb root, and/or senna — Consumers of these products will be adequately protected by information in the required label statement. Prohibiting sale of these products is unnecessary.

2. Take enforcement action against firms selling products containing aloe, buckthorn, cascara, frangula, rhubarb root, and/or senna — Even though no specific label statement is currently required, the Department could determine that the existing label failed to reveal material facts or consequences of customary use. Actions would have to be taken on a case by case basis and could be challenged by each firm. This approach would disrupt industry and confuse consumers with an assortment of label statements. Depending on the Department's resources, unlabeled products could remain in the marketplace for years posing an ongoing risk to consumers and creating market inequalities when consumers purchase unlabeled products believing they are safer.
3. Issue health alerts or press releases — These will not reach all the people at risk from these products and they are quickly forgotten while the risks and market inequalities remain.
4. Do nothing — FDA is considering issuing warning letters to industry or a policy statement that foods without informative labeling are misbranded for failing to reveal material facts. But compliance with warning letters and policy statements is erratic and enforcement problematic. FDA is not proposing new regulations at this time. Even if FDA were to propose new regulations, a final regulation could take years while the risks and market inequalities remain.

The emergency regulation requires no reports or any other written submissions by businesses.

Table 1 Summary of 67 Illnesses Following Consumption of "Dieter's" Teas Reported to FDA\* and FDB\*\*

Page 1

company	product	date	complaint
nutrition products	laci le beau dieters tea	08/18/95	chronic diarrhea after 4 months
nutrition products	laci le beau dieters tea	08/03/95	diarrhea twice a day
nutrition products	laci le beau dieters tea	07/18/95	stomach pains, muscle weakness
nutrition products	laci le beau dieters tea	06/07/95	palpitations, stomach cramps, stopped-constipated
nutrition products	laci le beau dieters tea	05/15/95	diarrhea, chills, faint, abdominal pain
nutrition products	laci le beau dieters tea	04/21/95	stomach cramps, diarrhea
nutrition products	laci le beau dieters tea	03/22/95	right abdominal and lower back pain, tea-lax
nutrition products	laci le beau dieters tea	01/15/95	colectomy after 6 bags per day for 2 years
nutrition products	laci le beau dieters tea	11/27/94	repeat fatigue, abdominal pain
nutrition products	laci le beau dieters tea	10/19/94	colitis, melanososis coli
nutrition products	laci le beau dieters tea	07/15/94	cramp, loose stools, pancreatitis
nutrition products	laci le beau dieters tea	05/22/94	diarrhea, weak, hospitalized w/ electrolyte imbalance
nutrition products	laci le beau dieters tea	05/16/94	cramp, diarrhea
nutrition products	laci le beau dieters tea	05/16/94	head ache, cramp, nausea, hand swell
nutrition products	laci le beau dieters tea	05/16/94	diarrhea, face swell
nutrition products	laci le beau dieters tea	10/08/93	cramps
puri-blend	puri-blend herbal tea	09/30/93	dehydration
fmali inc	good heart tea	08/13/93	burning itch
nutrition products	laci le beau dieters tea	07/09/93	abdominal pain-mid and upper right, melanososis coli
nutrition products	laci le beau dieters tea	06/25/93	diarrhea
slim for life	herbal balance	05/17/93	palpitation, headache
g s haly-simpson ale	dragonwell tea	04/28/93	dizziness
pinuli	victory mkts herbal tea	09/28/92	diarrhea
la flor products	herbs for brewing	06/25/92	poison
nutrition products	laci le beau dieters tea	06/15/92	other symptoms
health&energy	unknown	03/26/92	cramps
nutrition products	laci le beau dieters tea	02/18/92	other symptoms
lite&rite	thin herbal tune-up	01/21/92	other symptoms
seelect inc	seelect herb tea	11/24/91	chest pain
lite&rite	thinnergy	11/12/91	other symptoms
lifeway weight loss	unknown	09/23/91	nausea
nutrition products	laci le beau dieters tea	07/06/91	stomach pains
fmali inc	herbal tes	03/16/91	disoriented
nutrition products	laci le beau dieters tea	01/31/91	allergic reaction, hospitalized 4days
nutrition products	laci le beau dieters tea	01/30/91	diarrhea, cramp, rash
health venture co	nutri-slim dieter's tea	11/06/90	cold sweats
nutrition products	laci le beau dieters tea	10/31/90	cramps
nutrition products	laci le beau dieters tea	10/05/90	liver, other symptoms
j&d sales	morning rose diet tea	04/10/90	diarrhea
nutrition products	laci le beau dieters tea	04/04/90	diarrhea, dizziness
nutrition products	laci le beau dieters tea	03/26/90	diarrhea, loss of colon function
c&a enterprises	herbal starr herbs&vit	02/02/90	diarrhea
euro slim	euro slim	12/06/89	cramps
nutrition products	laci le beau dieters tea	07/15/89	cramps, severe
sunrider calli	tea whole food beverage	02/27/89	other symptoms
unknown	unknown	01/17/89	other symptoms
fronnier corp	herb tea herbs	09/28/88	cholinergic
seelect inc	seelect natural herb tea	06/22/88	diarrhea
nutrition products	laci le beau dieters tea	10/14/87	diarrhea
four D hobe	slim tea	03/04/87	other symptoms
nutrition products	laci le beau dieters tea	07/29/86	other symptoms
vincent tracing co	dieter green tea	02/03/86	other symptoms
nutrition products	laci le beau dieters tea	01/15/86	diarrhea, cramp
nutrition products	laci le beau dieters tea	10/15/85	diarrhea
nutrition products	laci le beau dieters tea	10/01/85	diarrhea

Table 1 Summary of 67 Illnesses Following Consumption of "Dieter's" Teas Reported to FDA\* and FDB\*\*

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company	product	date	complaint
nutrition products	laci le beau dieters tea	08/13/85	diarrhea
nutrition products	laci le beau dieters tea	05/17/85	drowsiness
JBR inc	east india herbal tea	04/18/85	nausea
vincent tracing co	dieter green tea	02/26/85	diarrhea
nutrition products	laci le beau dieters tea	02/25/85	other symptoms
natural sales co	tea	02/21/85	other symptoms
fmali inc	good heart tea	02/21/85	burning/itching
nutrition products	laci le beau dieters tea	01/03/85	other symptoms
four D hobe	internation slim tea	06/12/84	other symptoms
natural sales co	root tea	04/24/84	other symptoms
four D hobe	international slim	12/20/83	nausea
conco hlth prod	oriental trim	05/28/83	diarrhea



### Illnesses Reported to the California Department of Health Services Following Consumption of "Dieter's" Teas

date	sex	amount	frequency	durationn	steep	complaint
08/18/95	f	3 cup	daily	10 mnth	2 min	drank 3 cups a day, after meals to lose weight. developed chronic diarrhea after 4 months saw GI doc, negative for cancer, parasites. 2nd doc advised stop drinking tea
08/03/95	f	1 cup	daily	6-8 mnth	2-3 min	first time - cramps and "explosive", watery diarrhea - followed label directions exactly, commonly experienced two episodes of diarrhea a day, 4:00 AM & noon preceeded by cramps once steeped 5 min, severe cramps & diarrhea, if steep more than 3 min, throw out & start again
07/18/95	f	1 cup	daily	4 yr	3-5 min	used as a laxative, persistent stomach pains, muscle weakness muscle weakness only gradually improved over several months after stopping tea
06/07/95	f	2 cups	daily	1 yr	2-3 min	at first increased bowel movements cramps, occassional diarrhea later palpitations, stomach cramps, constipated when stopped, takes vicodin, diazide, procardia
05/09/95	f	1 cup	daily	1 year	10-15 min	drank to lose weight & for constipation during pregnancy -at first stomach cramps, loose stools stopped after hospitalized for 2 weeks with pancreatitis
05/09/95	m	3-4 cups	daily	4-5 wks	2-5 min	nausea, diarrhea, dehydration, weakness, hospitalized losing electrolyes Dr. recommended pediolyte, high BP taking aspirin & vasotec
05/04/95	f	1 cup	daily	6 yr	5min-5hr	cramps, no diarrhea, lower right abdominal pain - stopped when stopp'd drinking tea
04/21/95	f	2-3 cups	daily	3 months	?	stomach cramps, diarrhea
03/22/95	f	6 cups	daily	2-3 yr	?	colectomy for intractable constipation
03/22/95	f	?	daily	?	?	abdominal pain, use dieter's tea and occassionally smooth move as only laxatives
05/16/94	f	1 cup	once	1 day	?	headache, nausea, abdominal pain, diarrhea, neck & muscle ache, face flushing next AM face & fingers swollen
05/16/94	f	1 cup	once	1 day	?	immediate headache, abdominal cramps, nausea, hand swelling, fatigue, missed 3 days work
10/07/93	f	4 cups	once	1 day	10 min	6 hours after consumption - stomach cramps, nausea, light headed, fainting, vomiting, 12 hours after consumption - diarrhea lasting 3 days
02/19/91	f	1 cup	twice	2 days	3 min	hospitalized severe allergic reaction
02/19/91	f	1 cup	once	1 day	3 min	diarrhea, abdominal cramps, next morning difficulty swallowing, rash
07/15/89	m	1 cup	once	1 day	2 min	severe cramps

## Quantity of Sennosides A and B in Over-the-Counter Laxative Teas (milligrams, mg)

Brand/Flavor	Source	1b/8z/1m* mg A&B	1b/8z/2m* mg A&B	1b/8z/5m* mg A&B	1b/8z/10m* mg A&B	1b/8z/7m* mg A&B
Seelect Lax. Herb	CA	3	6	7	8	
Smooth Move	CA	3	10	14	10	10

## Quantity of Sennosides A and B in Teas Sold as Foods (milligrams, mg)

Brand/Flavor*	Origin	1b/8z/1m* mg A&B	1b/8z/2m* mg A&B	1b/8z/5m* mg A&B	1b/8z/10m* mg A&B
General Nutrition 24hr	CA	3	17	19	20
LLB** Original	CA	5	16	21	26
Trim Maxx Cinn.	NY	11	16	21	22
LLB Lemon Mint	CA	3	15	19	21
LLB Cinnamon	CA	2	14	22	20
Trim Maxx CranBlber	NY	6	14	21	23
Special Dieters	CA	13	14	20	28
LLB Irish Cream	CA	5	14	17	14
Natural Leaf Brand	Import	10	13	17	20
LLB Apricot	CA	6	12	16	10
LLB Cranberry	CA	5	11	14	14
LLB Amaretto	CA	6	11	13	13
LLB Peppermint	CA	7	10	17	13
Seelect Senna Leaf	CA	7	8	12	16
Ultra Slim	AZ	8	10	16	15

Average	6	13	18	18
Range	(2-13)	(8-17)	(12-22)	(10-28)

\* # bags/ounces boiling water/steeping time in minutes

\*\* LLB - Laci Le Beau

Tea prepared according to label directions

12 to 50 mg sennosides A and B once or twice a day is the effective dose in over-the-counter stimulant laxative drugs

## STATEMENT OF DETERMINATIONS

(a) The Department has determined that no alternative considered by the Department would be more effective in carrying out the purpose for which the emergency action was taken or would be as effective or less burdensome to affected private persons than the emergency action.

(b) The Department has determined that the proposed emergency regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with section 17500) of division 4 of the Government Code.

(c)(1) The Department has determined that the emergency regulation would not have a significant adverse economic impact on businesses, including the ability of California businesses to compete with businesses in other states. Three firms with national distributions (Body Breakthrough Inc., Deer Park, New York; General Nutrition Corporation (GNC), Pittsburgh, Pennsylvania; and Hobe Laboratories, Phoenix, Arizona) have informed the Department that they have ordered new labels bearing the language specified in the proposed emergency regulation. Current labels of Laci Le Beau, Super Dieter's Tea bear the label statement specified in the proposed emergency regulation. In

addition, a GNC representative informed the Department that GNC will begin requiring this labeling on all affected products distributed in their stores.

(c)(2) The Department has shared information on the proposed emergency regulation with representatives of 1) small and large business, 2) trade associations, 3) FDA, 4) other state health departments, 4) the Association of Food and Drug Officials, and 5) consumer groups. None of these representatives have expressed concern that this emergency regulation would have an adverse economic impact on California firms or firms doing business in California.

(d) The Department has determined that the proposed emergency regulation would affect small business since they would be required to comply.

(e) The Department has determined that it is feasible to draft the emergency regulation in plain English.

(1) Designate new Article 1 and Adopt new Section 10200 to read:

Article 1. Definitions

10200. Dietary Supplement.

(a) "Dietary supplement"

(1) Means an article (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) A vitamin,

(B) A mineral,

(C) An herb or other botanical,

(D) An amino acid,

(E) A dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or

(F) A concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) Means a product that

(A) Is labeled as a dietary supplement and

(B) Is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or if not intended for ingestion in such a form

(C) Is not represented for use as a conventional food, or as a sole item of a meal or the diet; and

(3) Does

(A) Include an article that is approved as a new drug in compliance with Health and Safety Code section 111550, subdivision (a) or (b), certified as an antibiotic under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. section 357, and/or licensed as a biologic under the Public Health and Safety Act, 42 U.S.C., section 262 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food, unless the article, when used as or in a dietary supplement under the conditions of use set forth in the labeling for such dietary supplement is adulterated under California Health and Safety Code section 110545, and

(B) Not include

1. An article that is approved as a new drug in compliance with Health and Safety Code section 111550, subdivision (a) or (b), certified as an antibiotic under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. section 357, and/or licensed as a biologic under the Public Health and Safety Act, 42 U.S.C., section 262, or

2. An article authorized for investigation as a new drug, antibiotic, or biologic for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

and which was not, before its approval, certification, licensing, or authorization, marketed as a dietary supplement.

(b) A dietary supplement may be a food or a drug, or both a food and a drug, as these terms are defined in Health and Safety code sections 109935 and 109925.

NOTE: Authority cited: Sections 100275, 110065, and 110100, Health and Safety Code. Reference: Sections 110175, 110290, 110545, 110620, 110625, 110630, 110660, 110705, 110760, 110765 and 110770, Health and Safety Code.

(2) Adopt new Section 10750 to read:

10750. Label Requirements for Foods and Dietary Supplements.

(a) Any food or dietary supplement, as defined in Title 17, California Code of Regulations, Division 1, section 10200, that contains any amount of a substance listed in Table 10750 A shall comply with the following:

(1) The label of foods and dietary supplements that have a total surface area available to bear labeling of 12 square inches or more shall bear the following notice in the manner prescribed in paragraph (a) (2) of this section:

NOTICE: This product contains (name of substance(s) and common name if different). Read and follow directions carefully. Do not use if you have or develop diarrhea, loose stools, or abdominal pain. Consult your physician if you have frequent diarrhea. If you are pregnant, nursing, taking medication, or have a medical condition, consult your physician before using this product.

(2) The notice required by paragraph (a) (1) of this section shall:

(A) Be enclosed by a 0.5 point box rule with 2.5 points of space around the notice,

(B) Utilize at least one point leading,

(C) Have a type that is kerned so the letters do not touch,

(D) Be all black or one color type, printed on a white or other neutral contrasting background,



(E) Utilize single easy to read type style such as Helvetica Regular and upper and lower case letters.

(F) Be in type size no smaller than 8 point.

(G) The word "NOTICE" shall be in all upper case letters, and

(H) The sentence "Do not use if you have or develop diarrhea, loose stools, or abdominal pain." shall be underlined and highlighted by bold or extra bold type, such as Helvetica Black.

(3) Foods and dietary supplements in small packages that have a total surface area available to bear labeling of less than 12 square inches shall include the notice required by paragraph (a) (1) in the format specified in (a) (2) in a package insert or a tag attached to the package and bear the following label notice in the manner prescribed in paragraph (a) (4) of this section:

NOTICE: Do not use if you have or develop diarrhea, loose stools, or abdominal pain. See package insert (or attached tag) for additional information.

(4) The notice required by paragraph (a) (3) of this section shall:

(A) Be enclosed by a 0.5 point box rule with 2.5 points of space around the notice,

(B) Utilize at least one point leading,

(C) Have a type that is kerned so the letters do not touch,

(D) Be all black or one color type, printed on a white or other neutral contrasting background.

(E) Utilize single easy to read type style such as Helvetica Regular and upper and lower case letters.

(F) Be in type size no smaller than 6 point.

(G) The word "NOTICE" shall be in all upper case letters, and

(H) The sentence "Do not use if you have or develop diarrhea, loose stools, or abdominal pain." shall be underlined and highlighted by bold or extra bold type, such as Helvetica Black.

(b) This section does not apply to foods and dietary supplements containing the leaf gel of aloe (*Aloe ferox* Mill. or *Aloe vera* (L.) N.L.Burm.) providing that the food or dietary supplement does not contain another substance listed in Table 10750 A.

Table 10750 A - Listed Substances

<u>Common Name</u>	<u>Plant Part</u>	<u>Botanical Name</u>
<u>aloe also known as</u> <u>cape aloe</u>	<u>latex</u>	<u><i>Aloe ferox</i> Mill.</u>
<u>aloe also known as</u> <u>aloe vera</u>	<u>latex</u>	<u><i>Aloe vera</i> (L.) N.L.Burm., also</u> <u>known as <i>Aloe barbadensis</i></u> <u>Mill. or <i>Aloe vulgaris</i> Lamk.</u>
<u>buckthorn</u>	<u>berry</u>	<u><i>Rhamnus catharticus</i> L.</u>

cascara also known as      bark

cascara sagrada

Rhamnus purshianus DC. also

known as Rhamnus purshiana

DC. or Frangula purshiana

(DC.) JG Cooper

frangula also known as      bark

buckthorn

Rhamnus frangula L. also

known as Frangula alnus Mill.

rhubarb root also known      root

as chinese rhubarb

Rheum officinale Baill.,

Rheum palmatum L., Rheum

rhaponticum L., or Rheum

tanguticum, Maxim. ex Balf.

senna also known as      leaf

Alexandria senna or      or pod

Tinnevelly senna

Senna alexandrina P. Mill.

also known as Cassia senna

L., Cassia angustifolia Vahl,

Cassia acutifolia Del., or

Senna angustifolia (Vahl)

Batka

<u>senna also known as</u>	<u>leaf</u>	<u><i>Senna obtusifolia</i> (L.) Irwin</u>
<u>sicklepod senna</u>	<u>or pod</u>	<u>and Barneby also known as</u>
		<u><i>Cassia obtusifolia</i> (L.)</u>
<u>senra</u>	<u>leaf</u>	<u><i>Senna tora</i> (L.) Roxb. also</u>
	<u>or pod</u>	<u>known as <i>Cassia tora</i> (L.)</u>

NOTE: Authority cited: Sections 100275, 110065, and 110100, Health and Safety Code.  
Reference: Sections 110175, 110290, 110660, 110705, 110760, 110765 and 110770, Health  
and Safety Code.