Deaths and bowel pain alleged:

Legal Snarl Allows Laxative To Be Sold as a ‘Dieters Tea’

I. The Tea
June H. Grell, age 37, died suddenly — and certainly unexpectedly — in her bed, in San Rafael, Cal., on July 20, 1991.
The autopsy attributed her “apparent natural” demise to an “undetermined” cause. The coroner added that June had suffered unexplained fainting spells several months earlier.
June Grell left an anguished, angry husband, Christopher E. Grell, he is a lawyer who practices in San Francisco. He wanted to know why his wife died, and he was — and is — driven to do something about it. He does not think her death was natural.

June had been dieting. For several months or more she had been drinking a popular, widely marketed herbal product called “Laci Le Beau® Super Dieter’s Tea®,” Grell said recently by phone. In a letter last year to FDA, Grell wrote: “I suspect that my wife’s sudden death . . . may have been caused by her use of Super Dieter’s Tea.”
The company denies this (See story, p. 5).

Reasons Cited
“[O]ne of the reasons I feel that this tea played a role in causing June’s death is because I specifically recall her using two of these tea bags in one cup of tea that she steeped for a good ten minutes the night she died,” Grell wrote in a letter last year to clinical toxicologist Timothy E. Albertson, M.D., at the University of California at Davis (Emphasis in the original). The directions on the package call for steeping one bag per cup, for two minutes, and for drinking a cup twice daily.
Toxicologist Albertson wrote back: “If this herbal tea has a weak diuretic [urine-producing] effect in most people, it is possible that it has a strong diuretic effect in a few . . . [which], if strong enough, could result in potassium wasting and set a person up” for diuretic-induced cardiac arrhythmias. But, Albertson cautioned: “It would be very difficult to prove this.”

No Warning on Box
The box that contained the tea bags, Grell told Albertson, did “not [have] a single warning or note of precaution.”
The box did say:
Since everyone’s system is different, it’s better to start with a small amount and gradually increase the amount to fit your needs.

Grell set out to discover what is in Laci Le Beau ® Super Dieter’s Tea ®; whether it could have killed his wife; and finally, what could be done to prevent another such tragedy. He eventu-
follow up

Cancer Hearing Is Political Show
Washington, D.C.

"Yes, sir!"

Judged by top health officials’ responses at a mid-April congressional hearing on fraud in breast cancer research, this is the one safe and politically correct answer when Rep. John Dingell (D-Mich.) is asking the questions and you are in the witness chair.

"The committee is known for having sharp teeth," Chairman Dingell confabulated at one point. "But it also is careful on whom we use them!"

Not too badly bitten in this encounter were the new chief of the National Institutes of Health (NIH), virologist Harold Varmus, M.D., and the chief of the National Cancer Institute (NCI), oncologist Samuel Broder, M.D. Dingell had called them to the Hill to explain their agencies’ role in the case of Montreal surgeon Roger Poisson, M.D. — who falsified data — and Pittsburgh surgeon Bernard Fisher, M.D. It was Fisher who led the huge, multi-center National Surgical Adjuvant Breast Project (NSABP), in which Poisson’s derelictions occurred.

Explanation Delayed

Through arrogance, old age, or a disastrous misreading of the political climate — it is not clear which — Fisher did not respond in a timely way to NCI requests that he quickly publish NSABP’s re-analysis of key findings, minus Poisson’s tainted data. Result: NCI forced Fisher to resign.

We covered the hearing of Dingell’s House Energy and Commerce Subcommittee on Oversight and Investigations, on April 13, because we had written very critically of his attacks on science and scientists for several years, but had never watched him, close up, in action. Also, our take on the Poisson case is radically different from that of some of our most esteemed reportorial colleagues — and we wanted to be sure we were right (PROBE, April).

Our view is that the Poisson fraud was not much of a story, until it was whipped up to colossal heights by the Chicago Tribune and New York Times. They thereby provided Dingell with three targets of opportunity: Poisson, who had admitted guilt; Fisher, who is a medical icon; and clinical research — which lately has become everybody’s whipping boy.

Our views were not changed by what we heard and saw in Dingell’s hearing room. The undeniable fraud in Montreal notwithstanding, Dingell is embarked on a political witch hunt, a la Sen. Joe McCarthy, with scientists substituted for “subversives” as the target.

Dingell Is Showman

This said, if it’s not your ox that’s being gored, Chairman Dingell is highly entertaining, as he bores in on a witness, gesturing for emphasis with a sharp-pointed yellow pencil.

"Vintage Dingell!" a Capitol Hill type seated near us mur-
Angry Activists Beseech Dingell To Validate Researchers’ Findings

Washington, D.C.

Palpable anger hung in the air in the congressional hearing room here as breast cancer activists and congresswomen deplored the scientific community’s “deceit and negligence.” They implored powerful House leader John Dingell (D-Mich.) to set matters aright.

The first witnesses called before Dingell’s subcommittee on April 13 were three activists. One of them, Jill Lea Sigal, of Alexandria, Va., 32 years old, had a breast cancer diagnosed late last year. She testified that she chose surgery based on this study as I did?

"How many women must now wonder, as I do, if they will die because they made the wrong decision? How many will die? We will never know."

But of course we will — and do: The answer, according to all available evidence, is none. Because there isn’t, and hasn’t been any allegation that Poisson fraudulently tipped the study’s findings toward lumpectomy.

**Dates Changed**

What he did do — and apparently about all that he did wrong as far as is known — was to change dates and other data to get some ineligible women admitted to the study before they were randomized to one treatment or the other. But Sigal was unwilling or unable to deal with these facts.

“Mr. Chairman,” she said to Dingell, “there seems to be no end to the fraud and deception. . . .

“Mr. Chairman, you and your committee have the authority and power to diminish or eliminate the possibility of this atrocity happening again by changing and strengthening the process.

“Mr. Chairman, thank you for holding this hearing and for doing what you can to correct this grave injustice.

We don’t gainsay Sigal’s fear. But we think people are supposed to do their homework before testifying to Congress.

**When ‘Quality’ Squelches**

“The history of . . . innovations . . . in medicine . . . indicates that the innovators are often erratic, unsystematic, and difficult to deal with. The quality controllers often regard the work as of poor quality and not worth publishing or noting. The only problem is that the quality controllers, while exquisite in their crossing of ‘t’s’ and dotting of ‘i’s,’ rarely discover anything that matters.” — David F. Horrobin, B.M.

*Journal of the American Medical Association*, March 9, 1990
Tea... continued from page 1

ally reported his wife’s case to both the U.S. Food and Drug Administration (FDA) regional office in San Francisco, and to the Food and Drug Branch (FDB) of the California Department of Health Services, in Fresno. One other fatality, at about the same time as June’s death, has been reported to FDA and FDB: A young woman in Palm Harbor, Fla., Debbie Helphrey, was drinking the Laci Le Beau® product, her mother told FDA and FDB, according to written reports, to lose weight in anticipation of her brother’s return from the Gulf War.

Herbal... continued from page 1

promote and sell herbal foods for medicinal purposes, such as: alfalfa herb for arthritis; ginger for circulation; and woody betony for heartburn.

The FDA regards such couplings as drug claims, which must be based on scientific evidence. But very few herbal products are approved by FDA as safe and effective nonprescription medicines, which would be the appropriate drug category. Many, in fact, have been banned in interstate commerce when sold as nonprescription drugs.

Some herbal products sold ostensibly as food may contain medicinal amounts of chemicals that FDA currently regulates as drugs. But, as foods, these products do not — indeed legally cannot — carry the important warnings that they would have to carry if sold as drugs. This is a dangerous Catch 22:

People buy and consume these unlabeled herbs, believing they are harmless at worst, when they may be hazardous.

Consumer advocates, as well as some FDA officials, want to end this double standard, and require medicinal herbs sold as foods to pass the same tests for safety, efficacy, and label disclosure that are imposed when they are sold as nonprescription drugs. Or, be tossed off the market.

But the health food industry and its millions of adherents prefer to weaken the FD&C Act, to facilitate the sale of herbal products bearing health claims. Powerful lawmakers, particularly Republican Senator Orrin Hatch of Utah, which is a leading herb-growing state are pushing legislation (the Dietary Supplement Health and Education Bill of 1993 [S. 784]) to this end.

The herbs issue thus is complicated by intersecting nutritional, medicinal, regulatory, legal, and commercial interests, including herb consumers’ intense belief in the plants’ healing powers, and their right to buy and use them without government meddling.

Starting with a death, the account here explores the regulatory impasse that has developed. This impasse has allowed one very popular but allegedly dangerous product to remain on the market, only loosely regulated, despite a decade of efforts by some FDA and California product safety officials to require that it carry appropriate warnings as a drug — or be banned. — D.R.Z.

“Debbie drank one 8 oz. cup of tea every night before she went to bed,” the mother wrote to FDB investigator Catherine L. Young. “She left the tea bag in boiling water until the water was luke warm.”

Tea Used Regularly

This, too, is much longer than the recommended two minutes. Mrs. Helphrey said her daughter drank the tea regularly for several months, and experienced cramps and loose bowel movements as “a reaction.”

An FDA investigator wrote that the autopsy report listed (1) electrolyte imbalance, (2) cardiac arrest, and (3) improper diet as the cause of death. The investigator added in his report that Debbie’s mother believes “habitual use” of the Laci Le Beau® tea contributed to it.

The investigator checked a box on his report form that said “FDA action indicated.” Other FDA officials who have investigated this tea have also checked that box.

In a letter to Young on file at FDB, a medical examiner in West Largo, Fla., said “it is my opinion that there was an association between [Debbie’s] death and the tea.”

He added:

“I do not, however, know if this was a direct cause and effect relationship due to some toxic effect of the tea, or whether the tea was just part of a weight reduction program which failed to provide proper nutrients. When she was hospitalized, she was found to have a low serum potassium level which dropped to a low of 1.9 mEq/L.” (Normal is above 3.4.)

If the tea was a diuretic, the medical examiner added, this would “implicate it more directly in the death.” He noted, too, that potassium depletion may result from “laxative abuse.”

Doctor Concurs

Debbie’s doctor agreed: Her electrolyte disturbance “appears to have been caused by dieting, and anything she took which would have a significant diuretic or laxative effect.”

In her letter to investigator Young, the mother added: “Many of Debbie’s friends drank this tea. They all thought it was healthy because it was purchased at a health food store.”

The tea’s distributor is listed on the box as Laci Le Beau Corp. In FDA and FDB files, prior to 1993, it is listed as Nutrition Products Company, of Fresno, Cal. The company said recently that the name has been changed to Laci Le Beau.

Documents Grell obtained through federal and California Freedom of Information (FOI) requests show that FDA and FDB also have received about two dozen other, non-fatal complaints, some serious, about the tea.

When the tea was first marketed, in 1984, the labels and promotional material contained medicinal claims, according to the FDA and FDB documents. Then, under pressure from these agencies, the medicinal claims were removed; the product is now sold as a food.

The company’s attorney, Jay H. Geller, Esq., of Los Angeles, told Grell in a letter last year: “The tea is not a drug, it is a food beverage.”

Geller went on to say: “The company is aware of no negative health effects from the consumption of its tea and none... continued on next page
Tea Is Flavorful Food, Company Says

"We try to give the tea drinker a lot of flavor," Laci Le Beau Corporation CEO Fred Stine said, from Fresno, Cal., in a telephone interview last month.

"We try to give them enjoyment in drinking an herbal tea, and our over all hope is to give a tea that people can really enjoy, and especially dieters," explained Stine, who returned a call placed to Earl Roberson, who is listed in U.S. and California documents as the company's owner.

But, Stine quickly added, the Laci Le Beau® Super Dieter's Tea® is not a dietary item, or part of any diet — and the company "doesn't say" that it is. It is caffeine free, he noted, and its purpose is to give dieters a break from the "blahs" of daily dieting.

"We have a good, flavorful product that people like," Stine said, in response to a question, "and it is probably very safe. Otherwise we'd have more complaints."

He said the company has been selling the tea for a dozen years, and has received possibly a dozen consumer complaints in that time.

Asked about the two deaths that have been reported in people who drank the tea (See main story), Stine declared: "I don't know of any complaints about deaths. But we manufacture herbal tea, and I doubt very much if herbal tea is going to have anything to do with that."

He added: "It would be my impression that if FDA or the state of California had records of people dying because of our product, we'd know about it, because they'd be in here talking about it immediately."

Asked what the tea's "lubricating herbs," mentioned on a package insert, do for dieters, Stine replied: "Well, probably nothing. Understand," he said, "that this is not a diet product."

Asked if the tea is safe, Stine replied: "Oh, most definitely. I know that Mr. Roberson drinks it himself ever since he started [making] it."

Laxative Carries Warnings

"This product may be considered an over-the-counter (OTC) drug item, contrary to a herbal tea," FDA inspector John A. Gonzales wrote in his report, "and perhaps should be marketed as a laxative."

Senna has a powerful laxative effect. It is sold as an OTC laxative drug under the name Senokot (Purdue Frederick), among others, where it carries this mandatory FDA warning: "Laxative products should not be used for a period longer than 1 week unless directed by a doctor."

No time limit or other warning appears on a recently-purchased Laci Le Beau® package. Quite to the contrary, continuing use is encouraged to "stay in shape." One early advertisement said: "The more diet tea you drink, the more weight you lose."

Senna's mode of action is not known. It is safe and effective as a stimulant laxative, according to FDA, when used in the recommended dosages of 12 to 50 mg of its active ingredients, sennosides A and B, once or twice daily, for up to a week.

Bowel Pain Common

A guide for pharmacists, the Handbook of Nonprescription Drugs (9th ed., American Pharmaceutical Health Association, 1990) warns: "All stimulant laxatives produce griping [severe spasmodic bowel pain], increased mucus secretions, and, in some people, excessive evacuation of fluid."

Herb experts are similarly cautious: One herbal warns that the sennosides in C. angustifolia are "cathartic" chemicals called anthraquinones; their main, medical use is to relieve constipation.

"They irritate the bowel wall, stimulating evacuation. Because of this action ... habitual use . . . is inadvisable since the bowel can quickly become dependent on it."

The herbal goes on to say: "Senna causes griping pains when used on its own, and is . . . usually combined with aromatics or digestive herbs such as ginger, cloves, dill, fennel, coriander, orange peel, or licorice."

The entry ends with this caution: "Avoid prolonged use."

An FDA inspector, Robert J. Anderson, visited Nutrition Products' small plant, in Fresno, in 1985. Based on interviews with the owners, Earl J. Roberson, and his wife, Helen, he said in his written report that the Super Dieter's Tea® is essentially senna tea. The other ingredients are "very minor," he added.

Asked last month if the product is a senna tea, Laci Le Beau CEO Stine said: "No, it is not. It is a tea that has in it C. angustifolia, seen in his report, "and it is probably very safe. Otherwise we'd have more complaints."

He added: "It would be my impression that if FDA or the state of California had records of people dying because of our product, we'd know about it, because they'd be in here talking about it immediately."

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*angustifolia*, a very mild form of a senna.*'

He added that it comes from cultivated *Cassia* trees in India; it is milder and contains less senna than *Cassia* from Egypt.

The FDAquantitates the medicinal dose of all senna products in milligrams of sennosides A and B. One *Senokot* tablet contains 8.6 mg of these sennosides. In 1986, the California Health Department's analytical laboratory found 15 mg of sennosides A and B per 2.3 gram tea bag of the dieter's tea, according to the lab's report.

The same year, Roberson told FDA's Anderson that the tea contained 6 to 8 mg sennosides A and B per gram, the agent reported." Each 2.3 gram tea bag thus might have contained 14 to 19 mg of these active ingredients.

Two years later, Roberson told Anderson, during a reinspection, that the teas contained 9 to 12 mg sennosides A and B per gram, or 21 to 28 mg per bag if each contained 2.3 grams.

In 1992 the product was reformulated, according to FDB's Young. She wrote that the company now gets ultraviolet spectrophotometric analyses of the senna leaves, and "then adjusts ingredient quantities... to achieve a maximum of 12 mg sennosides per 6 oz. brewed (2 minutes) serving."

One tea bag thus would be approximately the same as the minimal effective adult dose of medicinally-labeled senna laxative products.

However, Stine said last month by phone, "We shoot for a lot less than that. We look for between 2 and 6," in order to keep it "way below" the "laxative area."

"I have never heard anyone saying that this product is a laxative," Stine said, "because it is not."

He added: "It is certainly a food," and, citing the entry for senna in the Code of Federal Regulations (CFR 21, part 172.510), which categorizes items as foods, he said, "the amount of *Cassia* in our product falls in the flavoring category."

Among the other ingredients, *A. uva ursi* is listed as a diuretic in reference books. *A. officinalis*, has weak diuretic properties. Licorice is a laxative as well as a diuretic.

II. The Investigations

Federal and California officials did not wait for the two reported deaths to begin investigating the tea. FDA and FDB both have monitored it since soon after it entered the market.

The FDA is "actively investigating" the tea, consumer safety officer Lauri Love, M.D., a pathologist, said in February, from Washington, D.C.. FDB investigator Young, in Fresno, said in 1992 that she was "concluding" her investigation. But no final report appears in the FOI file released to Grell. No new regulatory action appears to have been taken.

Investigator Young did not respond to recent repeated phone requests for update and comment.

The company first ran afoul of FDB a decade ago, in April, 1984, when a Santa Barbara County official wrote, saying: "Product contains numerous herbal ingredients and appears to be represented as (but not properly labelled as) a drug."

Claims in ads, according to Young's report, included: "... one can enjoy a normal intake of food and at the same time, you may accomplish a weight loss."

"... causes a mild lubricating effect, ensuring proper elimination of excessive wastes."

On July 11, 1985, the FDA sent Roberson a certified notice of adverse findings. It said, "the labeling is false and misleading in that it states that 'one can enjoy a normal intake of food and at the same time, you may enjoy a weight loss.'"

The FDA said the tea was an unproven new drug, and noted that the agency was "unaware of any sound scientific studies demonstrating" that the tea is "of any benefit to dieters."

Hence, FDA compliance officer Ronald Fischer, in San Francisco, ruled, the tea's sale in interstate commerce is "prohibited."

**Product Changed to 'Food'**

The company did not remove the product from the market. Instead, it changed the label. It now marketed the tea as a food, a low-calorie beverage — and continues to do so.

A "note" on the package says, "As with all beverages, consult a physician before using if you are pregnant, lactating, on medication, or have a medical condition."

This is a standard cautionary note on *drug* products — but is not often found on foods such as coffee or tea plant teas.

A package insert in the tea says "first time users may experience minor stomach discomfort if the tea is steeped too long," and adds that "it is often normal to experience some increased bowel movements during the first two or three days after drinking Laci Le Beau ® Super Dieter's Tea ®."

The insert adds that it is the "ultimate dieter's beverage for... obtaining the support you deserve from mild, lubricating herbs."

This might be considered a laxative claim under FDA's...
Tea . . .
continued from preceding page

OTC Drug Review, which would require the product to be labeled as a drug.

Asked if the notes on the package are adequate for ensuring safe use, CEO Stine said, "Very much so!" He explained that the directions for use are important because "if you overbrew it, the bitters that are in the herbs start coming forward, and you get a lousy taste."

**Product Is Successful**

The product has been very successful.

One store owner told an FDA investigator in 1990 that the senna tea — which is sold under two or three other brand names as well as Laci Le Beau® — is "the highest volume single item sold in health food stores across the U.S." This owner, who said she had a degree in nutrition, also told FDA that the tea is "so dangerous" that she no longer sold it, the agent's report said.

In another FDA document, which Grell also obtained through FOI, agent John Gonzales quotes Roberson as claiming, in 1991, that over 50 million of the tea bags had been sold. Stine said by phone that the figure is now 100 million bags annually.

The "firm has refined its labeling to remove statements which might cause the product to be regulatorily classified as an unapproved new drug," Young wrote in her 1992 report. "Early labels demonstrate firm's awareness of the product's drug characteristics . . . In the past, these actions have been adequate to satisfy regulatory consideration, i.e., the change of labeling was acceptable to transform the product from an unapproved new drug to a food. The product was classified based on its labeling and not on its contents/ingredients."

The transition from mislabeled drug to health food occurs commonly, according to Allentown, Pa., psychiatrist Stephen Barrett, M.D., co-author of _The Health Robbers: A Close Look At Quackery in America_ (Buffalo: Prometheus, 1993):

"Companies in the health food industry market products with explicit therapeutic claims. When and if FDA tells them to stop, they back off — but try to retain as much of the original purpose as they can without making a frank claim."

**Defecation Affected**

Consumer complaints about the tea continued to trickle in to the two agencies in the early 1990s. By late 1992, FDB and FDA and the manufacturer had collected over a dozen complaints, according to a summary that Yowig prepared. One complaint sent to the company reported loose bowel move-
ments, and very bad pains. The complainant said that he (or she) stopped having bowel movements if he stopped drinking the tea. A similar complaint to FDA, in 1990, said the user drank the tea nightly, and after several months her colon stopped working; she wrote that she had "lost [the] ability to use [the defecatory] muscles."

These complaints are suggestive of a laxative dependence on the tea, according to Young.

Severe abdominal cramps were described in the majority of the complaints, along with diarrhea. One complaint to FDB described severe abdominal cramping every night after the tea was taken, after being brewed as directed on the package.

An FDA inspector visited the company in 1986 carrying complaints from consumers who had suffered diarrhea, cramping and other gastrointestinal symptoms. He reports:

"Roberson stated that the purpose of Super Dieter's Tea was as a mild laxative . . . but the State of California required them to remove those statements from their labels, so they are now selling it as a low calorie food. He stated that if people do not formulate the tea according to directions, many of them will experience diarrhea and cramping."

Roberson also said, according to the report, "the product is in essence a laxative."

**III. The Roadblock**

Investigator Young prepared a detailed case report with a stack of exhibits. The major conundrum, she writes, is whether the tea is a food or a drug. Earlier FDB reviews had decided, based on the labeling, that it was a food.

"It is this report's premise," she explains, "that it is the product contained in the package, not only the labeling on that package, that determines whether a product is a food or [a] drug [Emphasis added]."

The FDA's compliance policy "substantiates this approach," Young adds, citing an agency statement that "the removal of therapeutic claims from product labels does not automatically convert these products to food, especially in the absence of a history of food use for the products. . . ." The FDA has expressed its belief that the purpose of such relabeling is to circumvent the drug provisions of the Federal Food, Drug and Cosmetic [FD&C] Act . . . .

"However," the FDA guidelines go on to say, "when such relabeling occurs . . . the agency has found that it may be unable to prevent the marketing of these products in the absence of any scientific support that the products are toxic in the quantities offered for consumption."

Evincing her frustration, Young asks that in a further "technical review" of the tea, "the 'food' or 'drug' issues be transcended and set aside."

She writes:

The literature excerpts included in this report repeatedly refer to the same adverse conditions especially for prolonged use. Since the product is the same regardless of labeling as a food or drug, why are the food products allowed to be sold without warnings to the consumer, restrictions for dosage, etc.?

PROBE posed this question to Love and her associates at the continued on next page
Tea...

continued from preceding page

FDA's food branch, in Washington, D.C. They said one factor that influences FDA's regulatory purview over senna and other ingredients of Laci La Beau ® Super Dieter's Tea ® as a food, as distinct from a drug, is whether these substances are GRAS — pronounced grass — which means Generally Recognized As Safe. Foods, food supplements and food additives, including herbs, that are classified this way are assumed to be safe.

Robert L. Lake, FDA associate director for food policy planning, said recently by phone that senna, the tea's primary ingredient, is GRAS as "a flavor," albeit not as a primary ingredient.

Difficulties Cited

"We don't have a good handle at this point on what that would turn out to be as an amount," he added. He said that the agency could not ban a GRAS food, like senna, unless it could be shown that the amount contained in the product was "grossly" outside the amount needed for flavoring.

While senna is GRAS, A. uva ursi is not, and neither is it regulated as a food, FDA food safety expert, Manjeet Singh, said in a letter to Young. Neither is honesuckle, which, Singh adds, "is used in traditional Chinese medicine and has no history of food use."

To ban a food or food additive, Lake explained, the agency must show that the product is harmful. The statutory requirement for obtaining a court order to ban the use of a food is that it must be shown to be "ordinarily injurious," he said.

"We're not able to win a court case based solely on consumer complaints," he added. "We have to show, with scientific data, why this is a problem — and convince a judge."

PROBE asked Lake, who is an attorney, whether a product sold as a food, without drug warnings, can contain as much of an ingredient as is present in an approved drug, for which the warnings are mandatory.

"There is nothing as a matter of law that would prevent an overlap" between drug and food concentrations, he replied.

Legal Stricture Explained

"In the past, FDA has detained and barred many herbs from entry into this country on the basis that they had no history of common use as food in the U.S., and therefore did not qualify for GRAS status. . . . On Sept. 15, 1983, the U.S. Court of Appeals for the Ninth Circuit declared [this] regulation to be invalid. As a result . . . the agency can no longer impose such a restriction.

"The court ruling . . . make[s] it necessary for [FDA] to be prepared to demonstrate that a substance is not GRAS and thus is an unsafe food additive based upon scientific evaluation." — FDA Compliance Guidelines (1986)

"But as a matter of policy," FDA would not allow it.

He went on to say that he did not know enough about the dieter's tea to comment specifically — other than to say that FDA's food branch has received complaints, is concerned about them, and has not yet decided what to do.

Late last month, FDA spokesman Brad Stone said, "We're in process of trying to gauge the senna levels" in the tea.

Claims Count

At FDA's drug branch, spokesman Mike Shaffer said by phone, "I am not aware of any actions involving that product and that company at this time."

He explained: "What determines whether or not something is a drug is the claim that is made for it. It essentially doesn't matter what it really is. It's what the manufacturer claims it is that makes it a drug," meaning, he added, that only if the maker makes a medical claim, is the product a drug.

The FDA spokesman added that the "lubricating herbs" statement on the tea box "sounds like it might be unacceptable." He acknowledged that a lot of products carry claims that go beyond what FDA may think is acceptable.

Asked what would trigger the FDA drug branch's interest in the dieter's tea, Shaffer replied:

"One death would certainly be enough."