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March 12, 2001

FDA Commissioner Jane Henney
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Docket No. 00D-1598
Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or
Have not Been Developed Using Biotechnology

Dear Ms. Henney:

I am greatly opposed to your new "voluntary labeling" policy, which denies consumers a basic right to know. It is clear from this policy that the FDA does not want consumers to be able to identify whether the foods they eat have been bioengineered, which is also what the bioengineering food industry wants. Without mandatory labeling, neither consumers nor health professionals will know if an allergic or toxic reaction was the result of a genetically engineered food. Consumers will also be deprived of the critical knowledge they need to hold food producers liable should any of these novel foods prove hazardous.

The FDA "Voluntary Labeling" policy is wrong and must be changed for the following reasons:

1. **The policy denies American consumers the right to know what they are eating.**
2. **Bioengineering is a "material fact" requiring labeling according to FDA regulations.**
3. **You are doing bioengineering companies no favors by not requiring labeling.**
4. **The "Voluntary Labeling" policy is based on politics, not science.**
5. **Other countries require labeling of bioengineered foods, and the U.S. follows these requirements.**

1. The policy denies American consumers the right to know what they are eating.

Your agency admits to receiving more than 50,000 comments last year regarding genetically engineered foods. You concede: "Most of the comments that addressed labeling requested mandatory disclosure of the fact that the food or its ingredients was bioengineered or was produced from bioengineered food." Yet you ignore the will of the public saying the comments "did not provide data or other information regarding consequences to consumers from eating the food."¹

Whether genetically modified foods have known "consequences" is irrelevant to the right of consumers to know what they are eating. A vegetarian has a right to know whether the food she eats contains animal products. A person following kosher dietary laws has the right to know

¹ 66 FR 4839, 4840 (January 18, 2001).

whether the food she eats contains pork, shellfish, or any other nonkosher ingredient.² If there were no labeling requirements, vegetarians would not be able to discern whether food products contain animal matter, and a person following kosher dietary laws would not be able to tell whether the food was kosher.

If the FDA does not require labeling of bioengineered foods, a vegetarian may unknowingly eat a fruit or vegetable that contains an animal gene, and a person following kosher dietary laws may unknowingly eat a nonkosher ingredient. Once you permit the mixing of plants with animal genes you violate the First Amendment. By refusing to require the labeling of bioengineered food, you are restricting the free exercise of religion.³

Similarly, there are people such as myself who do not want to eat bioengineered foods. With the current policy of not requiring labeling of bioengineered foods, it is very difficult for me to avoid such products. Whether or not the FDA believes there are “consequences” does not affect my right to eat only what I want to eat.

2. Bioengineering is a “material fact” requiring labeling according to FDA regulations.

Many other food additives require labeling. Vitamins, minerals, artificial and natural colorings and flavorings all require labeling. Preservatives added to foods or packaging materials require labeling. Additives that change a food’s “mouthfeel” require labeling. Inserting a gene from one species into another is at least as material a change as is any other food additive. The bioengineering industry would not create a bioengineered food unless it was materially different from conventionally grown food. The FDA’s statements that bioengineering does not, by itself, make food “materially different” is neither correct nor based on science.

Here are some examples of bioengineered material changes to mass-produced crops:

1. According to the Monsanto Company, Roundup Ready soybeans and corn are “genetically improved” to tolerate Roundup Ultra herbicide.⁴
2. According to Monsanto, “the Roundup® family of herbicides will kill plants which do not express the Roundup Ready® gene.”⁵
3. According to Monsanto, “YieldGard® Insect Protected Corn is the first genetically improved Bt corn that offers season-long protection against European and Southwestern corn borers throughout the entire plant.”⁶

Because of these material differences, the FDA should require that all bioengineered food be labeled as such. Here are some examples of how to label bioengineered foods:

1. This corn was genetically engineered to survive spraying with “Roundup,” an herbicide.
2. This corn was genetically engineered with an internal insecticide.

² ARE GENETICALLY ENGINEERED FOODS IN ACCORD WITH JEWISH LAW? A Comprehensive Analysis of the Problems Prepared by Steven M. Druker Executive Director, Alliance for Bio-Integrity (A Concerned Jew) Copyright 1997.

³ Alliance for Bio-Integrity, et al. Plaintiffs v. Donna Shalala, et al. Defendants, Civil Action No. 98-1300 (CKK) Declarations of Rabbi Alan Green, June 24, 1999, and Rabbi Yossi Serebryanski, July 9, 1999.

⁴ Monsanto.com website (Farmsource/Products).

⁵ Id.

⁶ Id.

3. This product contains soy that was developed using biotechnology to survive spraying with the herbicide "Roundup."

Your declaration in the Guidance Document (p. 4) that biotechnology not affecting the characteristics of the food need not be labeled violates my right as a consumer to know what I am eating. As a consumer, I want to know not only that bioengineered food may have less saturated fat, but also that the crop survived spraying with an herbicide that can kill its non-bioengineered cousins.

The FDA does not, and cannot, know that there are no "consequences" from eating bioengineered foods. Corn has existed since before recorded history. Bioengineered corn has existed for only several years. Without mandatory long-term testing of these novel products, FDA cannot assert beyond doubt that there is no difference between corn and bioengineered corn. Your own FDA scientists stated that bioengineering is different from traditional breeding, and so are the risks.⁷ Your own scientists have stated that bioengineered foods are different from traditionally bred foods and should be tested prior to bringing these foods to market.⁸ Your Guidance Document (p. 2) states that the FDA has required special labeling if the absence of labeling would pose "environmental risks." The absence of labeling on all bioengineered foods does pose such an environmental risk. These bioengineered crops are harmful to the environment.⁹

Despite these risks, the FDA and the food products industry have decided to conduct a grand experiment on the American consumer. You have downplayed the environmental hazards of bioengineered foods.¹⁰ The truth is there has been ample evidence demonstrating that these foods are NOT "substantially equivalent" to non-bioengineered foods.¹¹ Bioengineered foods are materially different from traditionally bred foods in the following ways:

1. Bioengineered foods can cause allergies¹²
2. Bioengineering can change the nutritional value of food¹³

⁷ Discovery documents from the lawsuit Alliance for Bio-Integrity et al v Shalala, May 1998. Center for Food Safety, 666 Pennsylvania Ave, SE, Washington DC, 202-547-9359; Why FDA Policy On Genetically Engineered Foods Violates Sound Science And U.S. Law -- Statement of Steven M. Druker, J.D., Executive Director, Alliance for Bio-Integrity, Delivered at the FDA Public Meeting, Washington, D.C., November 30, 1999; Comments from Dr. Carl B. Johnson on the "draft statement of policy 12/12/91," January 8, 1992.

⁸ Comments from Dr. Louis J. Pribyl re: the "Biotechnology Draft Document, 2/27/92," March 6, 1992; Comments from Division of Food Chemistry and Technology and Division of Contaminants Chemistry. Subject: "Points to Consider for Safety Evaluation of Genetically Modified Foods. Supplemental Information," November 1, 1991.

⁹ Why FDA Policy On Genetically Engineered Foods Violates Sound Science And U.S. Law -- Statement of Steven M. Druker, J.D., Executive Director, Alliance for Bio-Integrity, Delivered at the FDA Public Meeting, Washington, D.C. November 30, 1999; Memorandum from Dr. Edwin J. Mathews to the Toxicology Section of the Biotechnology, Working Group. Subject: "Analysis of the Major Plant Toxicants," October 28, 1991; Memorandum from Dr. Samuel I. Shibko to Dr. James Maryanski, FDA Biotechnology Coordinator. Subject: "Revision of Toxicology Section of the Statement of Policy: Foods Derived from Genetically Modified Plants," January 31, 1992.

¹⁰ Note from Eric Katz (Dept. of Health & Human Services) to John Gallivan. Subject: "Food Biotechnology Policy Statement," March 27, 1992.

¹¹ E.g., Alliance For Bio-Integrity, et al. Plaintiffs v. Donna Shalala, et al. Defendants, Civil Action No. 98-1300 (CKK) Declarations Of Philip J. Regal, Ph.D., May 28, 1999, and John Fagan, Ph.D., May 28, 1999.

¹² Nordlee, J.D., Taylor, S.L., Townsend, J.A., Thomas, L.A. and Bush, R.K., 1996. Identification of a Brazil nut Allergen in Transgenic Soybeans. New England Journal of Medicine, Vol. 334(11), p. 726.

3. Bioengineered crops contaminate the soil with toxins¹⁴
4. Bioengineered crops harm animals other than those deemed "crop pests," including those beneficial insects which would otherwise help to control pests¹⁵
5. Bioengineered crops encourage the growth of pesticide resistant pests and weeds¹⁶
6. The modified genes may enter the human bloodstream, causing as yet unknown health problems¹⁷
7. Bioengineered crops increase the use of pesticides and herbicides¹⁸
8. Bioengineered crops discourage farmers from rotating their crops¹⁹
9. Bioengineered foods with antibiotic markers increase the likelihood of antibiotic-resistant bacteria²⁰
10. Bioengineered foods previously introduced have caused illnesses²¹

All these problems illustrate the facts that foods produced using bioengineering are "material facts" that must be disclosed under sections 403 (a) and 201(n) of the Food, Drug, and Cosmetic Act. FDA regulations indicate that genetic modifications are material facts when *consumers* view this information as important.²² The problems of bioengineered foods are not found in non-

¹³ Comments from Dr. Louis J. Pribyl re: "... the March 18, 1992 Version of the Biotechnology Document," March 18, 1992.

¹⁴ Saxena, D., Flores, S., Stotzky, G., 1999. Transgenic plants: Insecticidal toxin in root exudates from Bt corn. *Nature* 402, 480; Hill, H.R., 1994. OSU Study Finds Genetic Altering of Bacterium Upsets Natural Order. *The Oregonian*, August 8, 1994.

¹⁵ Ewen, S.W.B and Pusztai, A., 1999. Effect of diets containing genetically modified potatoes expressing *Galanthus nivalis* lectin on rat small intestine. *Lancet*, Volume 354, Number 9187, 16 October 1999; Birch, A.N.E., Geoghegan, I.E., Majerus, M.E.N., McNicol, J.W., Hackett, C.A., Gatehouse, A.M.R., Gatehouse, J.A. 1999. Tri-trophic interactions involving pest aphids, predatory 2-spot ladybirds and transgenic potatoes expressing snowdrop lectin for aphid resistance. *Molecular Breeding* 5(1): 75-83, 1999; Losey, J.E., Rayor, L.S., and Carter, M.E., 1999. Transgenic pollen harms monarch larvae. *Nature* 399:214; Hilbeck, A., Baumgartner, M., Fried, P.M., and Bigler, F., 1998; Effects of transgenic *Bacillus thuringiensis* corn fed prey on the mortality and development time of immature *Chrysoperla carnea* (Neuroptera Chrysopidae). *Environmental Entomology* 27 (2) 480-487; Do Genetically Engineered (GE) Crops Reduce Pesticides? The Emerging Evidence Says "not likely." Spring, 2000. A report by the World Wildlife Fund, Canada.

¹⁶ Huang, F., Buschman, L.L., Higgins, R.A. and McGaughey, W.H., 1999. Inheritance of resistance to *Bacillus thuringiensis* toxin (Dipel ES) in the european corn borer. *Science* 284:965-967; Do Genetically-Engineered (GE) Crops Reduce Pesticides? The Emerging Evidence Says "not likely." Spring, 2000. A report by the World Wildlife Fund, Canada; "50 Harmful Effects of Genetically Modified Foods," © 2000 Nathan B. Batalion, Published by Americans for Safe Food. Oneonta, N.Y.

¹⁷ *New Scientist*, January 30, 1999. Can we really stomach GM foods? Gut reaction; Shubbert, R., et al., 1998. Ingested foreign (phage M13) DNA survives transiently in the gastrointestinal tract and enters the bloodstream of mice. *Mol. Gen. Genet* 242: 495-504; Doerfler, W., and Schubbert, R., 1998. Uptake of foreign DNA from the environment: the gastrointestinal tract and the placenta as portals of entry. *Wien Klin Wochenschr*, 110(2):40-4.

¹⁸ Do Genetically-Engineered (GE) Crops Reduce Pesticides? The Emerging Evidence Says "not likely." Spring, 2000. A report by the World Wildlife Fund, Canada.

¹⁹ Id.

²⁰ Caplan, R. and Hickey, E. -- *Weird Science: The Brave New World of Genetic Engineering*, Pesticide Action Network North America and U.S. Public Interest Research Group, October 31, 2000.

²¹ "The Thalidomide of Genetic Engineering," L. R. B. Mann, D. Straton & W. E. Crist, Revised June 2000 from the GE issue of 'Soil & Health (NZ)' Aug '99.

²² Memorandum from Dr. Mitchell Smith, Head, Biological and Organic Chemistry Section, to Dr. James Maryanski, Biotechnology Coordinator. Subject: "Comments on Draft Federal Register Notice on Food Biotechnology, Dec. 12, 1991 draft," January 8, 1992.

bioengineered foods, and I do not want to expose myself to these substances. Yet your agency continues to ignore this evidence, and the wishes of consumers, in refusing to require mandatory testing and labeling.

Last year, Monsanto admitted to finding “unexpected gene fragments” in their bioengineered soybeans.²³ What other “unexpected gene fragments” are contained in other bioengineered foods? The truth is that the FDA does not know, because these experimental foods have not been subjected to adequate long-term testing. New proteins never before consumed by humans are being created and brought to market without any extensive tests being done to show that they are not causing allergies, cancer or other diseases.²⁴

In the case of bioengineered foods, the FDA has done a poor job of protecting the safety of consumers. Please remember that the potential allergies created by the ingestion of StarLink corn completely escaped the FDA regulatory guidelines. It was the EPA that discovered the digestive allergy concerns associated with StarLink corn.

3. You are doing bioengineering companies no favors by not requiring labeling.

Because I do not want to eat bioengineered foods, I have changed the way I shop. I have greatly increased the number and types of non-bioengineered and organic produce and groceries I eat. Here are some examples:

1. I stopped buying ANY mass marketed breakfast cereal containing corn. Corn has is a heavily bioengineered crop. If I want a corn cereal, I buy only organic cereal.
2. I asked a major breakfast cereal company if one of their popular cereals contained any bioengineered ingredients. They told me they could not be sure. Since they are not sure, I stopped buying this product. This was a difficult change for me, since I grew up with and continue to like this product. But my health and the environment are more important than one brand of cereal.
3. I buy only organic tofu and soy products. Soy is heavily bioengineered crop. If I see tofu or soy burgers at the grocery store, I will buy them only if they say “organic” or “no genetically modified ingredients” on the label.
4. I no longer buy mass marketed taco or corn chips, due to bioengineering. I buy only organic versions of these foods. The massive recall of StarLink corn, which was not and is not approved for human consumption, is a clear indication that the nation’s food distribution system cannot handle bioengineered food products in a responsible manner.
5. I buy more organic bread, pasta, and crackers. Wheat has not been tampered with bioengineering to the same extent as soy or corn, so I have not yet stopped purchasing non-organic wheat products. If your final rule goes through without mandatory labeling, I will

²³ Caplan, R. and Hickey, E. -- Weird Science: The Brave New World of Genetic Engineering, Pesticide Action Network North America and U.S. Public Interest Research Group, October 31, 2000.

²⁴ Alliance For Bio-Integrity, et al. Plaintiffs v. Donna Shalala, et al., Defendants, Civil Action No. 98-1300 (CKK), Declaration of Dr. Richard Lacey, M.D., Ph.D., May 28, 1999.

buy only organic bread and other wheat products, or products made without bioengineered ingredients.

6. I buy more organic fruits, vegetables, juices, and pasta sauces.
7. I buy food more frequently at grocery stores and supermarkets that carry many organic and non-bioengineered foods, such as Fresh Fields. I buy food less frequently at other supermarkets such as Giant or Safeway.
8. I buy only organic milk. Whatever the cow eats will end up in the milk.²⁵ I don't want to drink milk tampered with bioengineered ingredients in the cow feed.

In addition to grocery shopping, I have changed what I eat in restaurants. I no longer eat corn tortillas or chips in restaurants, because I have no idea whether the corn products contain bioengineered ingredients. I have reduced the amount of tofu and other soy products I eat in restaurants, for the same reason. There are many consumers like me who have changed their shopping and eating habits to avoid bioengineered food.

4. The "Voluntary Labeling" policy is based on politics, not science.

It is now public knowledge that in 1986 Monsanto and the Reagan Administration cut a deal by which Monsanto would develop bioengineered crops with the regulations it wanted.²⁶ Whatever Monsanto wanted, Monsanto got.²⁷ This deal was not to protect the consumer; it was to protect Monsanto. This deal has been carried through to the present,²⁸ which is why the FDA proposes only voluntary labeling. Since biotechnology companies did not want mandatory labeling, the FDA is not proposing mandatory labeling. Of course consumers have a concern about the unknown (Guidance Document p. 3). When an agency like the FDA ignores its own scientists about the risks of bioengineered food²⁹ and instead implement a political deals, consumers have every right to be concerned.

Monsanto's knew as far back as the 1980's that bioengineered foods had health and safety concerns, and that these concerns were reasonable.³⁰ But when Monsanto's management changed in the early 1990's, the company dismissed these health and safety concerns as "insignificant worries of the uninformed."³¹ Since the FDA followed whatever the Administration (and Monsanto) wanted, bioengineered foods would be tested "only if the company did it" and labeling "was ruled out as potentially misleading to the consumer."³²

²⁵ Memorandum from Dr. Gerald B. Guest, Director of the Center for Veterinary Medicine, to Dr. James Maryanski, Biotechnology Coordinator. Subject: "Regulation of Transgenic Plants--FDA Draft Federal Register Notice on Food Biotechnology," February 5, 1992.

²⁶ Biotechnology Food: From the Lab to a Debacle, The New York Times, January 25, 2001, Page A1, Col. 2-4.

²⁷ Id. page A1 col. 4.

²⁸ Id.

²⁹ Id. page C6 col. 5.

³⁰ Id. page C6 col. 3, 5.

³¹ Id. page C6 col. 5.

³² Id. page C6 col. 5.

U.S. producers of bioengineered foods should segregate these foods from non-bioengineered foods. They have already segregated bioengineered foods for export and for specific food items like baby food.³³ One producer of bioengineered foods, Aventis, already supports labeling and segregation of bioengineered foods from non-bioengineered foods.³⁴ Your Guidance Document (p. 6) states that "special handling may be appropriate to maintain segregation of bioengineered and nonbioengineered foods." I agree. Manufacturers of bioengineered foods should document and label their products at all stages of production and distribution so that there are no more "Starlink" accidents.

The Office of Management and Budget (OMB) reviews all rules prior to publication in the Federal Register. OMB has the reputation of favoring industry at the expense of the American citizen.³⁵ OMB may still be putting pressure on the FDA to keep the labeling of genetically engineered foods voluntary. Is this correct? Or are FDA officials deciding on their own to follow the wishes of the bioengineering industry over the wishes of the American people? I do not accept voluntary labeling, however this deal was reached. The FDA should stop caving in to the demands of the bioengineering industry. The FDA must work for the safety and rights of the American public.

The FDA has been accused of being a pawn of biotech industry. Documents such as your Draft Guidance for Industry lead many to feel this belief holds some truth. In your Draft Guidance you question whether manufacturers who choose not to use genetically engineered ingredients should be able to label their products as GMO Free. It is bad enough that the FDA does not now require the mandatory labeling of genetically engineered foods. Now your agency even seems to be exploring the idea of restricting the ability of a manufacturer to let consumers know the products are not genetically engineered. Such regulatory restrictions would be an outrageous act of censorship by the FDA.

5. Other countries require labeling of bioengineered foods, and the U.S. follows these requirements.

³³ Economic Impacts of Genetically Modified Crops on the Agri-Food Sector A SYNTHESIS, WORKING DOCUMENT, Directorate-General for Agriculture, March 31, 2000, page 37.

³⁴ The Aventis website states the following:

Aventis respects the consumer's right to choose, and will work with all of its stakeholders to facilitate the availability of both GMO and non-GMO derived food products. Aventis supports labeling of GMO produced food products, viewing it as a fundamental step in the future acceptance of biotechnology and genetically improved foods. This requires a number of measures, including the segregation of agricultural commodities and produce, clear and practical labeling guidelines, technical assistance for trace-ability, and the establishment of a threshold level for respective new DNA and protein.

www.aventis.com/cropsc/position/position.htm "Our position on . . . Labeling and Consumer Choice."

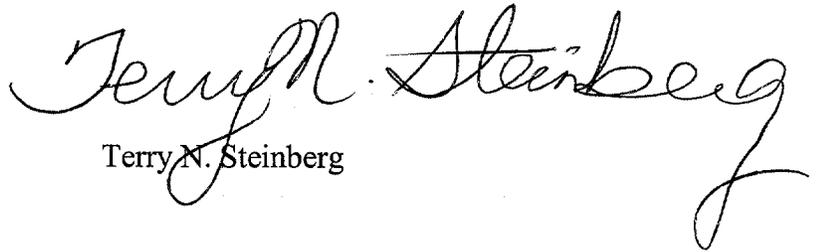
³⁵ See, e.g., memorandum from James B. MacRae, Jr. (of the Office of Management and Budget), for C. Boyden Gray (President Bush's White House counsel). Subject: "FDA Food Biotechnology Policy," March 21, 1992.

Genetically engineered foods are now required to be labeled in the European Union nations³⁶, in Japan³⁷, Australia and New Zealand³⁸, and other countries. Recently, both the E.U.-U.S. Biotechnology Consultative Forum and the Consumer Federation of America recommended mandatory labeling of genetically engineered foods. If the European Union and Japan can require labeling of genetically modified foods, there is no reason why the United States should not require labeling. If U.S. companies export genetically engineered food to Europe, the U.S. company must label the food as such.³⁹ If the U.S. company must label the food it exports to other countries, it should also be required to label the food for domestic consumption. Americans are no less deserving of this labeling than citizens of these other countries. The governments of these other countries have acted in the best interest of their people. The U.S. government, in contrast, has been acting in the best interest of bioengineering companies.⁴⁰

The FDA should take the following steps when revising the draft guidance document:

1. You must **require** that all bioengineered foods be labeled at all stages of the food distribution process.
2. You must continue to allow food manufacturers to label their products as having no genetically modified or engineered ingredients.

Sincerely,



Terry N. Steinberg

³⁶ Id. At 39.

³⁷ See www.spec.bc.ca/ge/background2.html Campaigns -- "Genetic Engineering -- Worldwide Opposition to GM Grows"

³⁸ See www.abc.net.au/science/slab/consconf/dinner.htm "Waiter, there's a gene in my food -- Who's Coming to Dinner," speaker, Dr Geoffrey Annison, Australian Food and Grocery Council, 1999.

³⁹ (same as FN 27)

⁴⁰ Biotechnology Food: From the Lab to a Debacle, The New York Times, January 25, 2001, Page A1, col. 2-4.

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