Association of Food and Drug Officials

2550 Kingston Road, Suite 311• York, PA 17402
Telephone (717)757-2888 • Fax (717)755-8089
E-Mail: afdo@blazenet.net • Internet: www.afdo.org

March 19, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering

The Association of Food and Drug Officials' Board of Directors, herein referred to as AFDO, is pleased to offer comments on this draft guidance document to assist the food industry about the voluntary labeling of food to indicate whether or not the food was developed using bioengineering.

Generally, we believe the guidance draft provides necessary and useful information to food businesses that desire to voluntarily provide label information about whether or not bioengineering was used to develop or produce the food. Overall, the draft is quite complete and understandable. For this reason, we will limit our comments to few key points to emphasize our support or point out areas where we have concerns or believe further guidance is necessary.

We agree that whether or not a food is the product of bioengineering, or does or does not contain bioengineered components, is not a "material fact" which would trigger mandatory labeling. However, we also agree that this guidance is necessary and *useful for those food businesses that desire to* ***voluntarily*** provide label information about whether or not bioengineering was used to develop or produce the food.

We note that the principles verification of label claims and evaluation of these claims in the context of the entire label are repeated throughout the guidance draft and believe theses premises provide the foundation essential to this guidance. We also find the concrete examples that are provided in the draft valuable in clarifying, expanding, and strengthening these principles.

We agree that labels that indicate that the food contains no bioengineered ingredients will be very difficult to verify and equally difficult to present in a way that does not imply that the food is superior. We believe the draft's suggestion is prudent that label claims about the absence of bioengineered ingredients should be restricted to comments about production or processing of the ingredients rather than their content. However, even claims about process need to be made cautiously to assure that these claims are both accurate and not misleading. Because we believe there is a high potential for labels to be misleading if a label claims either the total absence of bioengineered

ingredients or total isolation from the bioengineering process, we recommend that FDA strengthen its language to "strongly recommend" that the term "Free" (e.g., "GMO Free") not be used in bioengineering label statements.

Any claim about the absence of the use or effect of biotechnology in the production or processing of food *should not be allowed unless there is a system in place* to assure that a food or food ingredient produced or developed without the use of biotechnology are isolated throughout the processing and distribution system. For many agricultural commodities that are used widely as food ingredients (e.g., corn, soybeans), segregated handling is not the current norm. Developing preventive procedures and food handler understanding and compliance to ensure segregation of bioengineered ingredients from non-bioengineered ingredients will be a difficult and expensive process.

Unless there is a reliable analytical test for the presence of a specific bioengineered ingredient or until a verifiable isolated handling system is in place from the field to the packaging or retail sale location, we believe that the use of affidavits attesting to "non-use of biotechnology would not be useful or effective and should not be allowed. The use of affidavits would be effective only if used at each point in the production-distribution continuum where the potential exists for commingling of ingredients developed with and without the use of biotechnology. If affidavits or other verifiable record system were not in place at every potential commingling point, the affidavit system would be ineffective and may cause the label to be misleading.

We expect that in the future there will be an increased ability to analytically detect the presence (or absence) of bioengineered ingredients in support of label claims. To assist food businesses in developing labels that are not misleading when making claims about the presence or absence ingredients developed using biotechnology, we believe it would be helpful to both food businesses and consumers to establish a reliably attainable analytical threshold value that define the presence of bioengineered ingredients whenever possible. This threshold should be periodically be redefined and communicated as the analytical ability to reliably detect lower levels of bioengineered ingredients increases.

Whether voluntary label claims focus on the presence or absence of biotechnically developed ingredients, direct or implied claims about benefits related directly to the labeled food should:

- Use established criteria for scientific substantiation of the benefit claim
- Be evaluated in the context of the entire label
- Use the final version of this guidance in conjunction with existing requirements to assure that product labels are accurate, complete and not misleading.

As stated previously, we think this guidance is necessary, useful, and understandable. We appreciate and thank you for the opportunity to comment on this draft guidance.

Sincerely,

Steven B. Steinhoff
President
Association of Food and Drug Officials

SP013

FedEx USA Airbill

FedEx Tracking Number 811120064027

Form I.D. No. 0210

Recipient's Copy

1 From

Date 3-9-01

Sender's Name Steven Steinhoff Phone (608) 224-47[illegible]

Company DATCP FOOD SAFETY

Address 2811 AGRICULTURE DR FL 3 Dept./Floor/Suite/Room

City MADISON State WI ZIP 53718

2 Your Internal Billing Reference Information

3 To

Recipient's Name Dockets Management Branch Phone ( )

Company Food & Drug Administration

Address 5630 Fishers Lane Rm 1061 Dept./Floor/Suite/Room

(To "HOLD" at FedEx location, print FedEx address here)

☐ Check here if residence (Extra charge applies for FedEx Express Saver)

City Rockville State MD ZIP 20852

For HOLD at FedEx Location check here

☐ Hold Weekday (Not available with FedEx First Overnight)

☐ Hold Saturday (Not available at all locations) (Available for FedEx Priority Overnight and FedEx 2Day only)

For WEEKEND Delivery check here (Extra Charge. Not available at all locations)

☐ Saturday Delivery (Available for FedEx Priority Overnight and FedEx 2Day only)

☐ NEW Sunday Delivery (Available for FedEx Priority Overnight only)

811120064027

4a Express Package Service *Packages under 150 lbs.* Delivery commitment may be later in some areas.

☐ FedEx Priority Overnight (Next business morning)

☒ FedEx Standard Overnight (Next business afternoon)

☐ FedEx First Overnight (Earliest next business morning delivery to select locations) (Higher rates apply)

☐ FedEx 2Day (Second business day)

☐ FedEx Express Saver (Third business day)

FedEx Letter Rate not available. Minimum charge: One pound rate.

4b Express Freight Service *Packages over 150 lbs.* Delivery commitment may be later in some areas.

☐ FedEx Overnight Freight (Next business day)

☐ FedEx 2Day Freight (Second business day)

☐ FedEx Express Saver Freight (Up to 3 business days)

(Call for delivery schedule. See back for detailed descriptions of freight services.)

5 Packaging

☒ FedEx Letter ☐ FedEx Pak ☐ FedEx Box ☐ FedEx Tube ☐ Other Pkg.

Declared value limit $500.

6 Special Handling (One box must be checked)

Does this shipment contain dangerous goods?* ☐ No ☐ Yes (As per attached Shipper's Declaration) ☐ Yes (Shipper's Declaration not required)

☐ Dry Ice Dry Ice, 9, UN 1845 _____ x _____ kg.

☐ Cargo Aircraft Only

*Dangerous Goods cannot be shipped in FedEx packaging.

7 Payment

☐ Obtain Recipient FedEx Account No.

Bill to: ☐ Sender (Account No. in Section 1 will be billed) ☒ Recipient ☐ Third Party ☐ Credit Card ☐ Cash/Check

(Enter FedEx Account No. or Credit Card No. below)

Total Packages	Total Weight	Total Declared Value*	Total Charges
1		$ 1 .00	$

* When declaring a value higher than $100 per shipment, you pay an additional charge. See **SERVICE CONDITIONS, DECLARED VALUE, AND LIMIT OF LIABILITY** section for further information.

Credit Card Auth.

8 Release Signature

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.

321

Questions?

Call 1·800·Go·FedEx® (800)463-3339

0087512399

Rev. Date 3/98
Part # 153023PS
©1994-98 FedEx
PRINTED IN U.S.A.
GBFE 1/99