Tropicana®

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January 29, 2003

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

Re: Docket No. 02N-0209, Request for Comments on First Amendment Issues, 67 Fed. Reg. 34,942, May 16, 2002

Dear Sir or Madam:

Tropicana Products, Inc. (Tropicana) submits this letter in response to the Food and Drug Administration's (FDA) request for comments on First Amendment issues.

Tropicana is a leading producer of juice and beverage products. Tropicana manufactures, markets, sells, and distributes products under such well known trademarks as Tropicana Pure Premium, Tropicana Season's Best, Tropicana Twister, and (under license from Dole Food Company, Inc.) Dole.

Tropicana Pure Premium juices are not-from-concentrate (NFC). The freshly squeezed juice remains juice from fruit to palate. In contrast, their from-concentrate counterparts are manufactured by evaporating moisture from juice and later reconstituting the concentrate with potable water. This difference in production results in products significantly distinct in compositional and organoleptic qualities. Both types of juice typically are heat-pasteurized for safety.

Tropicana welcomes this opportunity to comment on First Amendment issues surrounding use of the term "fresh" on pasteurized NFC juices. Tropicana submits that, in keeping with judicial precedents regarding First Amendment protection of commercial speech, FDA should permit non-misleading, qualified claims using the term "fresh," such as "fresh-squeezed--pasteurized," in the labeling of pasteurized NFC juices. To the extent that the regulation governing "fresh" claims, 21 C.F.R. §101.95, and/or FDA's implementation of it, prohibit such claims, the regulatory practice is an unconstitutional prohibition upon commercial speech.

02N-0209

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I. DISCUSSION

A. FDA's "Fresh" Regulation

Section 403(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA) deems a food to be misbranded if its labeling is "false or misleading in any particular." 21 U.S.C. §343(a)(1). As part of its early 1990s rulemakings to implement the Nutrition Labeling and Education Act (NLEA), FDA promulgated a regulation governing use of the term "fresh" and related terms in food labeling. The agency's regulatory intent was to prohibit false or misleading "fresh" claims. 56 Fed. Reg. 60421, 60464 (Nov. 27, 1991). Paragraph (a) of the regulation provides:

> The term "fresh," when used on the label or in labeling of a food in a manner that suggests or implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation, except as provided in paragraph (c) of this section.

21 C.F.R. §101.95(a). Paragraph (c) provides that specific processes, including irradiation and refrigeration, do not preclude use of a "fresh" claim. 21 C.F.R. §101.95(c). Prefatory language in the regulation explains its reach:

> The terms defined in this section may be used on the label or in labeling of a food in conformity with the provisions of this section. *** However, the use of the term "fresh" on labels or labeling is not subject to the requirements of paragraph (a) of this section if the term does not suggest or imply that a food is unprocessed or unpreserved. For example, the term "fresh" used to describe pasteurized whole milk is not subject to paragraph (a) of this section because the term does not imply that the food is unprocessed (consumers commonly understand that milk is nearly always pasteurized). However, the term "fresh" to describe pasta sauce that has been pasteurized or that contains pasteurized ingredients would be subject to paragraph (a) of this section because the term implies that the food is not processed or preserved.

21 C.F.R. § 101.95.

Like milk cited in the above regulation, virtually all juices are heat-pasteurized to kill potentially deadly pathogens. Nevertheless, FDA apparently does not sanction any "fresh" claim, including a qualified claim, in labeling juice that has been pasteurized. *See, e.g.,* Warning Letter

to Stewart Brothers, Inc., SEA 02-55 (July 11, 2002) (available at <http://www.fda.gov/foi/warning_letters/g3414d.htm>). Tropicana believes that such strict prohibition of qualified "fresh" claims for pasteurized juice, based upon rote application of 21 C.F.R. §101.95, is constitutionally impermissible.

B. Commercial Speech Protection

The First Amendment to the U.S. Constitution comprehensively safeguards freedom of protected speech. In determining the degree of protection accorded, the U.S. Supreme Court has drawn a distinction between commercial speech and other forms of protected speech. *E.g., Ohralick v. Ohio State Bar Ass'n*, 436 U.S. 447, 455-56 (1978). 447 U.S. 557, 562-63 (1980). However, even commercial speech that principally "proposes a commercial transaction" is entitled to First Amendment protection. *E.g., Board of Trustees of the State University of New York v. Fox*, 492 U.S. 469, 473-74 (1989) [hereinafter Board of Trustees of SUNY]; *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York*, 447 U.S. 557, 562-63 (1980). It is well-established that food labeling claims, including "fresh" and similar claims, must be regarded, at a minimum, as commercial speech. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *United States v. General Nutrition, Inc.* 638 F. Supp. 556, 562 (W.D.N.Y. 1986).

The First Amendment protects commercial speech, such as food labeling claims, from unwarranted governmental intervention. *See Central Hudson*, 447 U.S. at 561; *Pearson*, 164 F.3d at 655. FDA is empowered to prohibit commercial speech in labeling that is false or misleading, 21 U.S.C. §§ 321(n), 343(a)(1); however, in order to be entirely prohibited, the label representation must be either inherently misleading or actually misleading, as opposed to only potentially misleading. *Peel v. Attorney Registration and Disciplinary Comm'n of Illinois*, 496 U.S. 91, 110 (1990); *In re R.M.J.*, 455 U.S. 191, 202-03 (1982); *Pearson*, 164 F.3d at 655. Any representation that is only potentially misleading may not be completely banned if it can be presented in a manner that is not deceptive. *Peel*, 496 U.S. at 100; *In re R.M.J.*, 455 U.S. at 203. Commercial speech that is not misleading also may be regulated; however, interference must be in proportion to the regulatory interest served, and it may be regulated only to the extent that such regulation furthers a substantial interest. *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 478 (1995), *In re R.M.J.*, 455 U.S. at 203-04.

The standard for determining the constitutionality of FDA's regulation of commercial speech is set forth in a four prong test provided in *Central Hudson*:

> At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading [prong one]. Next, we ask whether the asserted

> governmental interest is substantial [prong two]. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted [prong three], and whether it is not more extensive than is necessary to serve that interest [prong four].

447 U.S. at 556. Under this test, FDA may prohibit commercial speech, such as a qualified "fresh" claim, only if it is inherently false or misleading. Otherwise, the agency must demonstrate a substantial interest; the regulation in question (21 C.F.R. §101.95) must directly advance the asserted interest; and the regulation must not impose an unnecessary burden on the regulated food industry.

In justifying its restrictions upon protected commercial speech, the means the government chooses to accomplish its regulatory objective must be "narrowly tailored." *Board of Trustees of SUNY*, 492 U.S. at 480; *In re R.M.J.*, 455 U.S. at 203. In order to be narrowly tailored, FDA's restriction of "fresh" claims must be aimed at eliminating false or misleading claims "without at the same time banning or significantly restricting a substantial quantity of speech that does not create the same evils." *Ward v. Rock Against Racism*, 491 U.S. 781, 799 n.7 (1989); *see generally 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996)("bans against truthful, nonmisleading speech ... usually rest solely on the offensive assumption that the public will respond irrationally to the truth"). For this reason, regulatory requirements for disclosure, disclaimer, or explanation generally are highly favored and far less constitutionally suspect than regulations that entirely prohibit commercial speech. *Zauderer*, 471 U.S. at 650-01; *In re R.M.J.*, 455 U.S. at 203; *Pearson*, 164 F.3d at 657-58 (the Supreme Court has repeatedly pointed to "disclaimers as constitutionally preferable to outright suppression").

FDA's "fresh" claims regulation, 21 C.F.R. §101.95, as it applies to NFC juice fails the *Central Hudson* test because qualified "fresh" claims are not inherently false or misleading and the agency's interpretation of the regulation is not narrowly tailored to eliminate only false or misleading claims.

1. Qualified "fresh" claims for pasteurized juices are not inherently false or misleading.

Tropicana submits that certain "fresh" claims on processed juice products would be neither false nor misleading. Appropriate qualified claims, such as "fresh squeezed-pasteurized," would express to the purchasing consumer that the product was prepared directly from fresh fruit and not from concentrate, while revealing that the product has been pasteurized for safety. Such a claim represents a commercially viable way of truthfully distinguishing NFC juices from reconstituted juices. While reconstituted juices are required to declare "from concentrate" prominently on the

label,[1] in marketplace practice this disclosure typically is too small, lacks background contrast and/or is crowded among other label information; such ongoing violations escape enforcement activity. Moreover, use of the term, "pasteurized," on "fresh-squeezed- pasteurized" NFC juices would truthfully distinguish them from NFC juices that have not undergone heat-processing for safety.

The "fresh" regulation authorizes uses of the term "fresh" that do not imply that the labeled food is unprocessed. Tropicana believes that the claim "fresh squeezed-pasteurized," as applied to NFC orange juice, is just such a use.

As noted above, pasteurized whole milk may be labeled "fresh" because "the term 'fresh' used to describe pasteurized whole milk . . . does not imply that the food is unprocessed (consumers commonly understand that milk is nearly always pasteurized)." 21 C.F.R. § 101.95. Similarly, under FDA's mandatory juice HACCP rule (Procedures for the Safe and Sanitary Processing and Importing of Juice, 66 Fed. Reg. 6137 (Jan. 19, 2001)), nearly all juices will be pasteurized or subjected to some form of alternative food safety processing technology. As the rule is implemented and enforced, it will make NFC juice, like milk, a product known by consumers to be nearly always pasteurized or otherwise processed. Applying the same rationale to use of the qualified claim, "fresh-squeezed," in describing pasteurized NFC juice is only reasonable. The addition of the word "pasteurized" (*i.e.*, "fresh squeezed-pasteurized") removes any possibility that consumers might be misled.

FDA permits other appropriately qualified "fresh" claims such as "fresh frozen" and "packed from fresh [ingredient]" in labeling processed foods. 21 C.F.R. § 101.95(b); Letter to William J. Spain, Senior Vice President, Technology, Del Monte Research Center, from Elizabeth J. Campbell, Acting Director, Office of Food Labeling, Center for Food Safety and Applied Nutrition, FDA (Apr. 3, 1998) (FreshCut brand canned fruits and vegetables may claim "packed from fresh _____" and "made with fresh _____"). Again, the rationale for allowing such claims is that these terms do not suggest or imply that the finished food is unprocessed. Rather, these claims accurately denote for consumers foods that have
been processed using a fresh ingredient(s). A "fresh-squeezed—pasteurized" claim for NFC orange juice would do the same.

2. A regulation that expressly or through implementation prohibits truthfully qualified "fresh" claims for pasteurized NFC juices is not narrowly tailored and places an unnecessary burden on industry.

Inasmuch as properly qualified "fresh" claims are not inherently or actually misleading as applied to pasteurized juice, FDA may not ban such claims entirely. Yet, as presently implemented,

[1] 21 C.F. R. § 146.145(c).

21 C.F.R. § 101.95 does precisely that. Any FDA regulation of "fresh" claims for pasteurized NFC juice must satisfy the four-prong *Central Hudson* test. As presently implemented, the regulation fails the requirements of *Central Hudson.*

Certainly, FDA has a legitimate, substantial interest in prohibiting false or misleading "fresh" claims, and 21 C.F.R. § 101.95, properly applied, advances that interest. However, the regulation as it is being implemented is not narrowly tailored as applied to properly qualified claims for pasteurized NFC juice. Implementation of 21 C.F.R. § 101.95 is far more extensive than is necessary to advance the legitimate government interest in prohibiting truly misleading "fresh" claims.

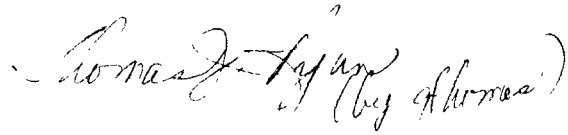
Thus, 21 C.F.R. § 101.95 is constitutionally infirm as applied to pasteurized NFC juice because it bans truthful, qualified "fresh" claims along with false and misleading claims. Where, as here, further speech can cure a potentially misleading claim, the Constitution favors disclaimers and disclosures over outright bans. *See Pearson* 164 F.3d at 657-58. Constitutionally, FDA may not ban a truthful "fresh-squeezed" NFC juice claim when that claim can be qualified to disclose that the NFC juice is also "pasteurized." Moreover, the ban does not serve consumer interests because it forbids juice makers from distinguishing fresh-squeezed, pasteurized juice from the concentrate imposter.

II. CONCLUSION

The U.S. Supreme Court, in construing the First Amendment, explicitly has instructed that "the free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful." *Zauderer*, 471 U.S. at 646. Moreover, the Court has directed that, in choosing between a paternalistically restrictive regulatory approach and one that fosters open communication, FDA must choose the latter because "[i]t is precisely this kind of choice, between the dangers of suppressing information, and the dangers of misuse if it is freely available, that the First Amendment makes for us." *Virginia State Board of Pharmacy*, 425 U.S. at 770. We urge FDA to permit use of qualified, non-misleading "fresh" claims, such as "fresh squeezed-pasteurized," for NFC juices in accordance with First Amendment protection of commercial speech. Such a decision can be easily and quickly implemented through the issuance of a letter or Guidance.

Tropicana appreciates this opportunity to submit its comments in response to FDA's request for information concerning First Amendment issues.

Respectfully submitted,



Thomas J. Ryan
Senior Vice President and General Counsel

cc: The Honorable Daniel E. Troy, Esq.
Chief Counsel