



Headquarters: 400 N. Tampa Street/P. O. Box 1531/Tampa, Florida 33601/813-273-6572 Fax: 813-273-4396

February 15, 2002

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

Docket Number: **cf0161**

Dear Sir or Madam:

On behalf of the member companies of National Juice Products Association ("NJPA"), we appreciate the opportunity to comment on the draft guidance document released for comment on December 21, 2001 and related to exemptions from the warning label requirement for fruit juices. A list of NJPA's member companies is enclosed with this letter.

NJPA recommends that FDA not publish the proposed guidance until thorough consideration has been given to FDA Chief Counsel Daniel Troy's letter dated January 22, 2002 regarding juice HACCP (as corrected by letter dated January 25, 2002), and to the Citizen Petition (Docket No. 02P-0009/CPI) filed by NJPA, Florida Citrus Processors Association and the State of Florida, Department of Citrus. Both of these documents directly relate to the draft guidance document, the single facility requirement mentioned therein, and the question "When in the process should the 5-log pathogen reduction be applied?" (Copies of Mr. Troy's letters are enclosed with these comments.)

NJPA urges that the warning declaration required on juice products that do not achieve the 5-log pathogen reduction at point of final product packaging pursuant to 21 CFR 101.17(g) should not be construed to apply to high °Brix concentrated fruit juices where the 5-log (or greater) pathogen reduction effected during concentration is maintained and risks of recontamination are controlled in accordance with the terms and conditions outlined at page 2 of Mr. Troy's January 22, 2002 letter. The draft guidance document, which was released for comment prior to Mr. Troy's January 22, 2002 letter, should be updated to include the guidance expressed in that letter. This would be consistent with past interpretations and guidance issued in conjunction with 21 CFR 101.17(g).

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We also urge FDA to issue any guidance only after taking into account the considerations contained in Mr. Troy's letter of January 22, 2002, as they relate to both warning statements for frozen concentrated fruit juices and appropriate control measures for the transportation and handling of concentrated juices.

Ansley Watson, Jr., Executive Director  
Direct Line (813) 273-4321

Kristen C. Gunter, General Counsel  
Direct Line (941) 680-9908

Tammy G. Andis, Executive Secretary  
Direct Line (813) 273-4330

Dockets Management Branch  
February 15, 2002  
Page 2

Thank you for your consideration. If NJPA can be of any assistance, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink, appearing to read "Ansley Watson, Jr.", written in a cursive style.

Ansley Watson, Jr.  
Executive Director

AWjr/kcg/a  
Enclosures

**NATIONAL JUICE PRODUCTS ASSOCIATION  
MEMBERSHIP LIST 2001-02**

- |     |                            |     |                               |
|-----|----------------------------|-----|-------------------------------|
| 1.  | A. LASSONDE, INC.          | 32. | LE VIGNOBLE, S.A.             |
| 2.  | AMERICAN FRUIT PROCESSORS  | 33. | LOUIS DREYFUS CITRUS          |
| 3.  | BASCITRUS AGRO INDUSTRIA   | 34. | MAUI PINEAPPLE                |
| 4.  | CANADAIGUA CONCENTRATES    | 35. | MCCAIN CITRUS, INC.           |
| 5.  | CARGILL CITRO-AMERICA      | 36. | MINUTE MAID                   |
| 6.  | CCPI/VALLEY FOODS          | 37. | NESTLE                        |
| 7.  | CITROFRUT, S.A.            | 38. | OCEAN SPRAY CRANBERRIES       |
| 8.  | CITROSOL, S.A. DE C.V.     | 39. | OLD ORCHARD BRANDS            |
| 9.  | CITROSUCO NORTH AMERICA    | 40. | OLYMPIC FOODS, INC.           |
| 10. | CITRUS BELLE, DIV. A. DUDA | 41. | ORFIVA, S.A.                  |
| 11. | CITRUS WORLD, INC.         | 42. | PASCO BEVERAGES               |
| 12. | CLEMENT PAPPAS & CO., INC. | 43. | PEACE RIVER CITRUS PROD.      |
| 13. | CLIFFSTAR CORPORATION      | 44. | PEPSICO, INC.                 |
| 14. | CONFRUTTA, S.A.            | 45. | PITTRA -CAMERICAN             |
| 15. | COUNTRY PURE FOODS         | 46. | SAN JOAQUIN VALLEY            |
| 16. | CUTRALE CITRUS JUICES USA  | 47. | SILVER SPRINGS CITRUS COOP    |
| 17. | DEL MONTE FOODS            | 48. | SOCIEDAD COOPERATIVA          |
| 18. | DEL ORO, S.A.              | 49. | SOUTHERN GARDENS CITRUS       |
| 19. | DELANO GROWERS GRAPE       | 50. | SUNDOR BRANDS, INC.           |
| 20. | DINTER GMBH                | 51. | SUNKIST GROWERS, INC.         |
| 21. | DOLE PACKAGED FOODS        | 52. | SUNPURE                       |
| 22. | FLORIDA FLAVORS, INC.      | 53. | SUN-RYPE                      |
| 23. | FLAVORS FROM FLORIDA       | 54. | TECNOVIN DO BRASIL ICIE, LTDA |
| 24. | GOLDEN GEM GROWERS, INC.   | 55. | TEXAS CITRUS EXCHANGE         |
| 25. | GIVADAUN ROURE             | 56. | TICOFRUT, S.A.                |
| 26. | GREGORY PACKAGING INT'L    | 57. | TREE TOP, INC.                |
| 27. | H.J. HEINZ COMPANY         | 58. | TROPICANA PRODUCTS, INC.      |
| 28. | JOHANNA FARMS, INC.        | 59. | VENTURA COASTAL CORP.         |
| 29. | JUGOS DEL SUR, S.A.        | 60. | VERY FINE PRODUCTS, INC.      |
| 30. | JUGOS CONCENTRADOS         | 61. | VICENTE TRAPANI, S.A.         |
| 31. | THE KROGER CO.             | 62. | VIE DEL COMPANYY              |
|     |                            | 63. | VITA-PAKT CITRUS PROD. CO.    |
|     |                            | 64. | WELCH'S                       |

## ASSOCIATE MEMBERS

1. A.G. EDWARDS & SONS
2. ANDERSON COMPANY
3. B.A. CARLSON OF FLA.
4. BEN HILL GRIFFIN, INC.
5. BOWEN JUICES INT'L
6. BROWN INTERNATIONAL
7. BYNUM TRANSPORT
8. CARLOS STEFFENS, INC.
9. CHAMPION INTERNATIONAL
10. CITRICO, INC.
11. CITRUS ASSOC. N.Y COTTON
12. COMBIBLOC
13. CONTINENTAL PLASTIC
14. DIRECTUS INTERNATIONAL
15. ENERFAB
16. ELOPAK, INC.
17. EXPORT PACKERS CO. LTD.
18. FABRI-KAL CORP.
19. FERREIRO AND COMPANY
20. FIMAT FUTURES USA, INC.
21. FLEMING PACKAGING
22. FLORIDA WORLDWIDE CIT.
23. FMC CORPORATION
24. FMC do BRASIL
25. FOOD TECHNOLOGY SERVICE
26. GRAHAM PACKAGING COMPANY
27. HARTOG FOODS INT'L
28. INDIAN RIVER TRANSPORT
29. INTERNATIONAL FRUIT CONC.
30. INTERNATIONAL PAPER
31. ITI FOODS
32. JEFFERSON SMURFIT CORP.
33. KENDALL FROZEN FRUITS
34. KOCH MEMBRANE
35. MID-FLORIDA FREEZER
36. MILLER & SMITH FOODS
37. OAKLEY GROVES, INC.
38. PAINE WEBBER
39. PREMIER JUICES, INC.
40. PRUDENTIAL SECURITIES
41. PURKEL PRODUCTS, INC.
42. RABOBANK
43. RAHAL FOODS
44. RYAN TRADING CORP.
45. SCHOLLE CORP.
46. SETHNESS-GREENLEAF
47. SMITH BARNEY SHEARSON
48. SONOCO PRODUCTS CO.
49. TAMPA BULK SERVICES
50. TRADEWIND FOODS INT'L
51. VINCENT CORPORATION
52. WHITE CAP, INC.



Office of the Chief Counsel  
Food and Drug Administration  
5600 Fishers Lane, GCF-1  
Rockville, MD 20857

January 22, 2002

Robert P. Parker, Esq.  
Paul, Weiss, Rifkind, Wharton, & Garrison  
1615 L Street, N.W.  
Washington, D.C. 20036-7420

Re: Citizen Petition of the Florida Dept.  
of Citrus, et al concerning Juice HACCP

Dear Mr. Parker:

This letter reiterates the position of the Food and Drug Administration regarding the enforcement of the "single facility" requirement<sup>1</sup> in the juice HACCP final rule,<sup>2</sup> which we discussed at our January 15 meeting.

On January 10, 2002, the Florida Department of Citrus, the Florida Citrus Processors Association, and the National Juice Products Association submitted a citizen petition.<sup>3</sup> The petition asked that FDA (1) amend the juice HACCP final rule to exempt processors of shelf-stable and concentrated juice products from the "single facility" requirement; and (2) stay the effective date of the requirement until the Agency had disposed of the citizen petition. The petitioners contend that transportation hazards (which the "single facility" requirement was designed to address<sup>4</sup>) could be adequately addressed as part of a processor's HACCP plan. Petition at p. 3-4. At our meeting,

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<sup>1</sup> The relevant portion of the so-called "single facility" requirement provides that "Processors claiming an exemption under paragraph (a)(1) or (a)(2) of this section [which includes the juice concentrate producers in question] shall also process and perform final product packaging of all juice subject to the claimed exemption within a single production facility operating under current good manufacturing practices." 21 CFR 120.24 (c).

<sup>2</sup> 66 Fed. Reg. 6138 (January 19, 2001).

<sup>3</sup> Although the issues discussed at the January 15 meeting and in this letter are raised in the citizen petition, this letter is not a response to that petition. FDA will respond to the petition consistent with 21 CFR 10.30.

<sup>4</sup> See 66 Fed. Reg. at 6172-6173.

Robert P. Parker, Esq.  
January 22, 2002  
Page 2

representatives of the Florida juice industry described in some detail the measures they represented are used widely by Florida juice concentrate producers to ensure that concentrates are not contaminated after processing when shipped to another facility for final packaging. The industry representatives argued that, in light of these measures, the "single facility" requirement is unnecessary for these producers.

Based in part upon this presentation and these representations, FDA has agreed to consider the exercise of enforcement discretion with respect to the "single facility" requirement as applied to producers and users of high °Brix juice concentrate.<sup>5</sup> FDA is considering the exercise of its discretion where the following three conditions are satisfied: (1) the producer and the user establish appropriate prerequisite and sanitation standard operating procedures (SSOPs) for the transport of high °Brix juice concentrate; (2) the producer and user designate as a critical control point (CCP) in their respective HACCP plans the transport of high °Brix concentrate from the production facility to a second facility for formulation and final packaging of concentrates; and (3) the producer and user establish control measures to prevent, reduce, or eliminate the risk of recontamination of the concentrate during transport.<sup>6</sup> The Agency expects that any producer of high °Brix juice concentrate whose HACCP plan does not designate such transport as a CCP and establish appropriate control measures will comply with the "single facility" requirement on the effective date of the final rule.<sup>7</sup>

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<sup>5</sup> High °Brix juice concentrate is a concentrate that is diluted and repackaged as either frozen orange juice concentrate for consumer use or as institutional concentrate.

<sup>6</sup> FDA does not intend to consider the exercise of its enforcement discretion for producers and users of high °Brix juice concentrates that are diluted to single strength and repackaged.

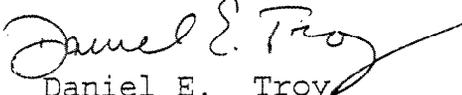
<sup>7</sup> The final rule has staggered effective dates for juice processors of various sizes. The rule is effective January 22, 2002, for all processors except small processors and very small processors, as defined in the regulation; the rule is effective January 21, 2003, for small processors, and January 20, 2004, for very small processors.

Robert P. Parker, Esq.  
January 22, 2002  
Page 3

As noted, the petition also requests that the final rule be amended to exempt producers of shelf-stable juices from the "single facility" requirement. In light of our January 15 discussion, FDA is considering the exercise of enforcement discretion only for the bulk transport and repackaging of shelf-stable single strength juice that is transported in aseptic packaging.

The agency intends to develop and promptly issue guidance that will contain FDA's basic recommendations for appropriate control measures for several transport modalities, including tankers, mobile tank farms within cargo ships, single-use sanitary containers (e.g., bag-in-box containers), and reusable containers with single-use liners (e.g., 55 gallon drums with single-use liners). In issuing this guidance, FDA will adhere to the Agency's Good Guidance Practices (GGPs), 21 CFR 10.115.

Please call me at 301-827-1137 or Catherine Copp of my staff at 301-827-1139 if you have any questions regarding the Agency's position. Technical questions should be directed to Terry Troxell, Ph.D., director of the Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, at 202-205-4064.

Sincerely,  
  
Daniel E. Troy  
Chief Counsel

cc: William S. Stinson, Jr., Ph.D.  
Florida Department of Citrus

Ansley Watson, Jr.  
Kristen C. Gunter  
National Juice Products Association

Robert L. Garfield  
American Frozen Food Institute

Lawrence P. Higgins  
Pasco Beverage Group

Robert P. Parker, Esq.  
January 22, 2002  
Page 4

Lucy Reid  
The Minute Maid Company

L. Richard Tomlin  
Louis Dreyfus Citrus Inc.

Lisa Young Rath  
Florida Citrus Processors Association

Sean H. Frielich  
Vitality Beverages, Inc.

Allen Matthys, Ph.D.  
National Food Processors Association



Office of the Chief Counsel  
Food and Drug Administration  
5600 Fishers Lane, GCF-1  
Rockville, MD 20857

January 25, 2002

Robert P. Parker, Esq.  
Paul, Weiss, Rifkind, Wharton, & Garrison  
1615 L Street, N.W.  
Washington, D.C. 20036-7420

Re: Citizen Petition of the Florida Dept.  
of Citrus, et al concerning Juice HACCP

Dear Mr. Parker:

I am writing to correct a minor error in my letter to you of January 22. Footnote 5 of that letter should have read as follows:

High °Brix juice concentrate is a concentrate that is diluted and repackaged as either frozen juice concentrate for consumer use or as institutional concentrate.

I apologize for any confusion or inconvenience this error may have caused.

Sincerely,

*Daniel E. Troy /cll*  
Daniel E. Troy  
Chief Counsel

cc: William S. Stinson, Jr., Ph.D.  
Florida Department of Citrus

Ansley Watson, Jr.  
Kristen C. Gunter  
National Juice Products Association

Robert L. Garfield  
American Frozen Food Institute

Lawrence P. Higgins  
Pasco Beverage Group

Robert P. Parker, Esq.  
January 25, 2002  
Page 2

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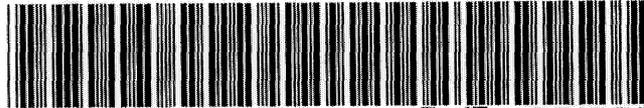
From: ANSLEY WATSON (813)273-4200  
MACFARLANE FERGUSON & MCMULLEN  
400 N. TAMPA ST. SUITE 2300  
  
TAMPA, FL, 33602



To: Dockets Management Branch (HFA-305) (301)827-6860  
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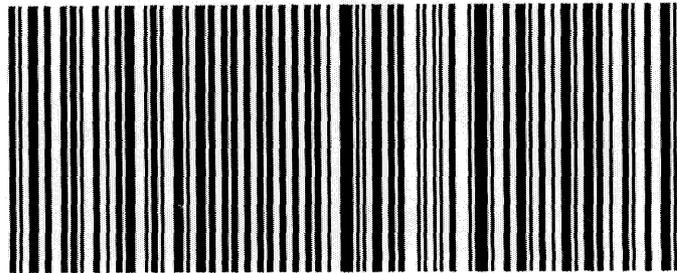
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