



JUL 1 2005

1900 5 JUL -6 P1:34

Diane B. McColl
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Dear Ms. McColl:

This is in response to your letter to the Food and Drug Administration (FDA) dated March 25, 2005, requesting written confirmation of our March 7, 2005 telephone conversation regarding the labeling of the color fixatives, ferrous lactate and ferrous gluconate on black olive products. Upon receipt of this letter, you have agreed to withdraw Citizen Petition 96P-0230 on behalf of Purac America Inc.

On June 25, 1996, you submitted a citizen petition on behalf of Purac America Inc. to amend Title 21 of the Code of Federal Regulation (CFR) 101.4(b), to grant an exception for the label declaration of ingredients for black olives that allows the use of language indicating that one of the color fixatives, ferrous lactate or ferrous gluconate may not be present in the olives. As you may know, FDA regulations in 21 CFR 101.4(a)(1) provide that ingredients required to be declared on the label or labeling of a food shall be listed by common or usual name in descending order of predominance by weight. Further, the regulation also provides for the use of "and/or" labeling in the ingredient declaration for certain types of ingredients, but not for color fixatives. Purac America Inc. requested that FDA authorize a similar exemption for the color fixatives ferrous lactate and ferrous gluconate for further flexibility in the manufacturing of black olives.

As we discussed on March 7, 2005, the color fixatives, ferrous lactate and ferrous gluconate may be identified simply as "color added" (or by an equally informative term that makes clear that a color additive has been used in the food) in the ingredient declaration for black olive products as provided in 21 CFR 101.22(k)(2). The term "color added" will allow olive processors to use either ferrous lactate or ferrous

96P-0230

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gluconate without changing the ingredient declaration on the label or in the labeling for their black olive products.

Should you have additional questions, please do not hesitate to contact me.

Sincerely yours,



Loretta A. Carey
Consumer Safety Officer
Food Labeling
and Standards Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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*NOT ADMITTED IN DC

DIRECT DIAL (202) 737-4291

March 25, 2005

Ms. Loretta Carey
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling and Dietary Supplements, HFS-820
5100 Paint Branch Parkway
College Park, Maryland 20740

Re: Citizen Petition 96P-0230

Dear Ms. Carey:

Based on your comments during our March 7, 2005 telephone conversation, we understand that the color fixatives ferrous lactate and ferrous gluconate may be identified simply as "color added" in the ingredient declaration for black olive products as provided in 21 C.F.R. § 101.22(k)(2). We understand further that use of the term "color added" will allow olive processors to use either ferrous lactate or ferrous gluconate without changing the ingredient statement on the label or in the labeling for their black olive products.

In view of the foregoing, we are prepared, on behalf of Purac America Inc., to withdraw Citizen Petition 96P-0230 upon receipt of written confirmation from your office of the above-described permissible ingredient designation for color fixatives in black olive products.

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(949) 553-7400
FAX: (949) 553-7433

4819 EMPEROR BOULEVARD
SUITE 400
DURHAM, NORTH CAROLINA 27703
(919) 313-4750
FAX: (919) 313-4751

Ms. Loretta Carey
March 25, 2005
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Please contact me as soon as possible if you have any further questions regarding the petition.

Sincerely,

A handwritten signature in cursive script that reads "Diane B. McColl".

Diane B. McColl

DBM/dh

LAW OFFICES

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F. GAIL BORMEL
FRANCES K. WU*

*NOT ADMITTED IN DC

June 25, 1996

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

95 JU -2 8:10:01

CITIZEN PETITION

The undersigned, on behalf of Purac America Inc., submits this petition pursuant to 21 C.F.R. §§ 10.30 and 10.40, to request the Commissioner of Food and Drugs to amend the requirements for designation of ingredients for foods, specifically 21 C.F.R. § 101.4(b), to grant an exception for the label declaration of ingredients for black olives that allows the use of language indicating that one of the color fixatives ferrous lactate and ferrous gluconate may not be present in the olives.

A. ACTION REQUESTED

The petitioner requests that FDA amend section 101.4(b) of its food labeling regulations to add the following subparagraph:

() Iron salts that act as color fixatives in black olives (ferrous lactate and ferrous gluconate) may be

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declared in the ingredient statement, in order of predominance appropriate for the total of all iron salts in the food, by stating the specific common or usual name of each individual iron salt in descending order of predominance in parentheses following the collective name "color fixatives." If the manufacturer is unable to adhere to a constant pattern of iron salts as color fixatives, the listing of the individual iron salts need not be in descending order of predominance. Iron salts used as color fixatives and not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as "or", "and/or", "contains one or more of the following:".

B. STATEMENT OF GROUNDS

1. Applicable Statutory and Regulatory Provisions

The Federal Food, Drug, and Cosmetic Act (FDC Act) requires that the label of a food that is fabricated from two or more ingredients bear "the common or usual name of each such ingredient." 21 U.S.C. § 343(i)(2). However, it also provides that to the extent that compliance with this requirement "is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated" by FDA.

Agency regulations provide that "ingredients required to be declared on the label or labeling of a food ... shall be listed by common or usual name in descending order of predominance by weight" 21 C.F.R. § 101.4(a)(1). Based on the statutory

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authority cited above, the regulations also currently provide certain exemptions from this requirement to list each ingredient by common or usual name. These exemptions are found in section 101.4(b), which currently allows "and/or" labeling for certain types of ingredients.

"And/or" labeling enables a manufacturer to list together in the ingredient list all the ingredients of a particular type that it sometimes uses to make the product, without having to specify the ingredients that are actually present in the product. To make clear that not all of the ingredients identified are actually present, the entry in the ingredient list must include the terms "or," "and/or," or "contains one or more of the following." FDA regulations currently authorize the use of "and/or" labeling for fats and oils (when they are not a predominant ingredient), leavening agents, yeast nutrients, dough conditioners, and firming agents. 21 C.F.R. §§ 101.4(b)(14), (16)-(19).

Petitioner requests that FDA authorize a similar exemption for the color fixatives used in black olives, ferrous lactate and ferrous gluconate.

2. Iron Salts Used as Color Fixatives in Black Olives

Ferrous gluconate and ferrous lactate are iron salts that are used as color fixatives for olives ripened by lye treatment and oxidation, *i.e.*, black olives. Ferrous gluconate is the iron salt predominantly used by olive processors in the United States. Ferrous lactate is currently used by many olive manufacturers in Spain, the world's leading producer of olives, and in Portugal, Italy, and other olive-producing countries. Ferrous gluconate is currently "listed" as a color additive and is exempt from

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certification when "used in amounts consistent with good manufacturing practice for the coloring of ripe olives." 21 C.F.R. § 73.160(c). Ferrous lactate is the subject of a pending petition (No. 3G0396) to affirm its GRAS (generally recognized as safe) status as a color fixative in black olives.^{1/} This GRAS affirmation petition was filed by the petitioner herein.

3. The Need for an Exemption

Olive processors in the U.S. welcome the flexibility of using either ferrous lactate or ferrous gluconate as color fixatives in black olives because they can substitute another iron salt when one is in short supply and can take advantage of price fluctuations and use the most economical iron salt at the time of packing. However, they have expressed concerns about the need to maintain two separate label stocks - labels listing ferrous gluconate as the color fixative and labels listing ferrous lactate as the color fixative. "And/or" ingredient labeling would enable processors to use either ferrous salt, without having to change their labels each time they use a different ferrous salt.

"And/or" labeling would also benefit private label purchasers who may need to buy processed olives from more than one processor due to fluctuations in olive crop yields. These private labelers could purchase black olives from any processor

1/ When FDA, on its own initiative and shortly after the Color Additives Amendments were enacted, listed ferrous gluconate as a color additive, the agency assumed that ferrous gluconate was used to impart color to the olives. However, as data submitted with petition 3G0396 show, both ferrous gluconate and ferrous lactate are used to fixate the black color that results from the lye treatment and oxidation.

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without having to maintain separate stocks of labels in order to match the particular salt in use by the selling processor. In addition, if a processor's olive supplier cannot meet the processor's demand, the processor could buy processed olives from another processor, and use its own existing labels regardless of the iron salt used by the selling processor.

Because the iron salts used as color fixatives in black olives are present in the olives in insignificant amounts, the exact identity of the iron salt used is not a material fact for the consumer. There are no special dietary, health or religious reasons for requiring that the exact iron salt be identified on the label of black olives.

a. Difficulty in Adhering to Constant Pattern of Use

An olive processor may find it necessary to use either ferrous gluconate or ferrous lactate, depending upon the current market supply and price of each agent. Ferrous gluconate is derived from gluconic acid. The price of gluconic acid is influenced by the price of potato starch, which is the feed stock for the fermentation of gluconic acid. In addition, the world's largest producers of gluconic acid/ferrous gluconate have their manufacturing sites in Europe. Most of the olive processors in California use ferrous gluconate made in Germany. The price of ferrous gluconate is thus affected by the exchange rate of the U.S. dollar versus the European currencies.

Ferrous lactate is derived from lactic acid. The price of lactic acid is influenced by the price of beet and cane sugar, as sugar is the main feed stock for lactic acid fermentation. The largest producer of lactic acid, and the only producer of ferrous lactate, is the petitioner herein, which manufactures both lactic

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acid and ferrous lactate in Europe. Thus, the price of ferrous lactate is also affected by the exchange rate of the U.S. dollar versus the European currencies.

For the past five years, the price of both ferrous gluconate and ferrous lactate has fluctuated between \$2 per pound and \$4 per pound.

If FDA grants this petition, olive processors will be able to make purchases that take advantage of the price fluctuations of the color fixatives and use the most economical iron salt at the time of packing. That is, processors will have the flexibility to respond to fluctuations in price and availability and to respond to marketplace factors without having to change food labels. These lower production costs could help to reduce the price that consumers pay for the processed black olives.

In addition, depending on the crop yields of a processor's particular olive supplier(s), the olive processor who uses ferrous gluconate may need to buy processed olives from other processors who use ferrous lactate (and vice versa) in order to meet the demands or needs of customers. Exhibits A and B illustrate the fluctuations in olive crop yields and prices of olives from 1983 to 1995. "And/or" ingredient labeling would allow these processors to use existing stock labels for the olives processed by others and avoid maintaining multiple stocks of labels. Again, this would help to reduce production costs and could lead to lower prices for the consumer.

Due also to fluctuations in crop yields, private label purchasers often need to buy processed olives from more than one processor, i.e., processors that use ferrous gluconate and processors that use ferrous lactate. The private labeler, whose

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labels are often made up many months in advance of the packing season, has no way to control or predetermine the ferrous salt that will be the most economical or most available at the time of packing. If FDA authorizes the use of "and/or" ingredient labeling for the color fixatives used in black olives, the private labelers will have the flexibility to purchase processed black olives from different processors without having to maintain separate stocks of labels and change their labels each time they need to use a different processor in order to match the particular salt in use by the processor.

b. Ferrous Salts are Minor Ingredients

The ferrous salts used as color fixatives in black olives are present in the olives in very small quantities. In the case of ferrous lactate, the typical concentration of iron remaining in the treated olives is 10-40 ppm. In addition, the consumer is not purchasing the iron salts; the consumer is purchasing black olives. Therefore, the exact identity of the iron salt used in the olives is not a material fact for the consumer.

c. There are No Special Dietary, Health, or Religious Reasons to Require Exact Identification

There are no special dietary, health, or religious reasons for requiring that the exact iron salt be identified. Consumers who wish to avoid specific iron salts for any reason will continue to have enough label information to avoid them if they so choose by not selecting black olive products.

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C. ENVIRONMENTAL IMPACT

An environmental impact statement is not required for this petition, pursuant to the categorical exclusion in 21 C.F.R. § 25.24(a)(ii).

D. ECONOMIC IMPACT

Information concerning economic impact is not required unless explicitly requested by the Commissioner. 21 C.F.R. § 10.30(b).

E. CERTIFICATION

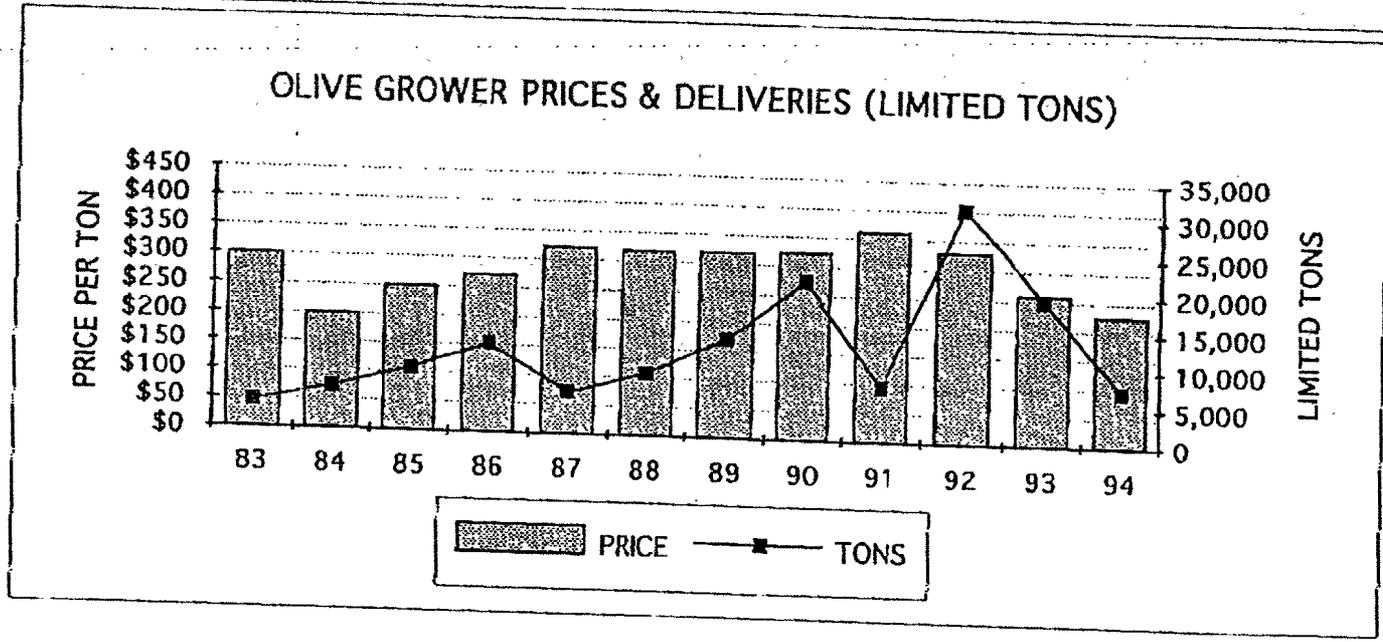
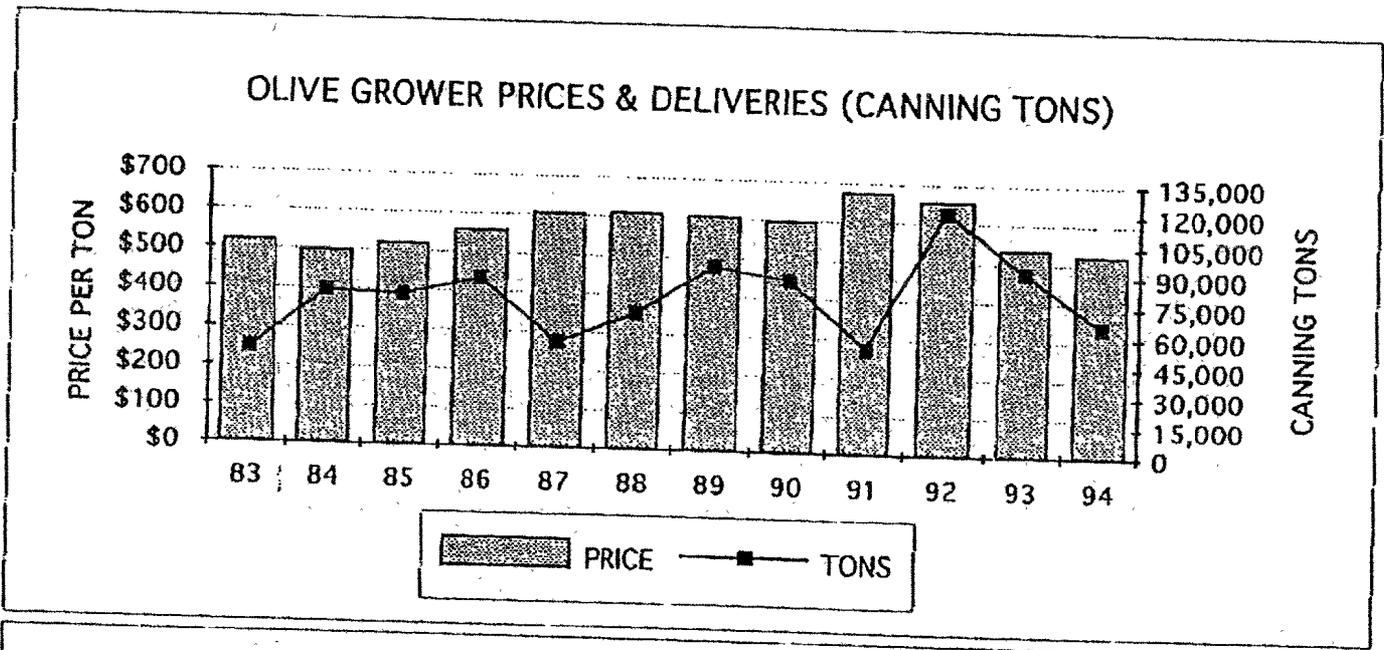
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that the petitioner is not aware of information that is unfavorable to the petition.

Respectfully submitted,

HYMAN, PHELPS & McNAMARA, P.C.
Counsel for Purac America Inc.

By: Samia N. Rodriguez
Samia N. Rodriguez

EXHIBIT A



**CALIFORNIA OLIVES - GROWER PRICES
1983-84 TO 1994-95**

YEAR	Canning Size		Limited Size	
	Tons	Avg. Price \$	Tons	Avg. Price \$
1983-84	47,722	521	3,606	300
1984-85	76,411	498	5,702	200
1985-86	74,944	517	8,416	250
1986-87	83,519	557	11,905	271
1987-88	53,281	605	5,484	321
1988-89	68,000	611	8,376	318
1989-90	92,115	606	13,217	319
1990-91	86,089	598	21,274	322
1991-92	53,023	676	7,235	360
1992-93	120,745	654	31,175	329
1993-94	91,835	539	19,465	260
1994-95	65,515	523	7,448	226

Average price - Independent canner price not including standard bonus,
extra bonus or hauling allowance

Prices based on data compiled by Olive Growers Council

SOURCE: COC, OGC

Butler, Jennie C

From: Szybist, Lynn
Sent: Wednesday, May 25, 2005 2:11 PM
To: Butler, Jennie C
Subject: RE: Purac America, Inc. Petition_96P-0230

My fax number is 301-436-2636. Please send me the acknowledgement letter and interim response, too.
Thanks,
Lynn

-----Original Message-----

From: Butler, Jennie C
Sent: Wednesday, May 25, 2005 2:09 PM
To: Szybist, Lynn
Subject: RE: Purac America, Inc. Petition_96P-0230

Hi Lynn:

This docket is not electronic. Please give me your fax number and I'll have it faxed to you. Do you need the acknowledgement letter and interim response?

Jennie

-----Original Message-----

From: Szybist, Lynn
Sent: Wednesday, May 25, 2005 11:33 AM
To: Butler, Jennie C
Cc: Szybist, Lynn
Subject: FW: Purac America, Inc. Petition_96P-0230

Hi Jennie,

Would you be able to send me a copy of this petition or let me have access to it electronically?
Thank you,
Lynn

301-436-1432

-----Original Message-----

From: Carey, Loretta A
Sent: Tuesday, May 24, 2005 8:38 AM
To: Szybist, Lynn
Subject: Purac America, Inc. Petition

Hi Lynn,

I could not find my copy of the petition but the petition number is 96P-0230. Dockets will send you a copy if you ask them. Hope you had a good time away. Thanks.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC 24 1996

25/11 '96

DEC 27

A10:01

Ms. Samia N. Rodriguez
Hyman, Phelps, & McNamara, P.C.
Counsel for Purac America Incorporated
700 Thirteenth Street, N.W.
Washington, D.C. 20005

Re: Docket No. 96P-0230/CP1

Dear Ms. Rodriguez:

This refers to your citizen petition, dated June 25, 1996, and filed July 2, 1996, requesting that the Food and Drug Administration amend 21 CFR 101.4(b), to grant an exception for the label declaration of ingredients for black olives that allows the use of language indicating that one of the color fixatives, ferrous lactate or ferrous gluconate, may not be present in the olives.

In accordance with 21 CFR 10.30(e)(2), this letter is to advise you that we have not been able to reach a decision on your petition within the first 180 days of its receipt because of other Agency priorities and the limited availability of resources.

Sincerely yours,

for F. Edward Scarbrough, Ph.D.
Director
Office of Food Labeling
Center for Food Safety
and Applied Nutrition

96P-0230

LETI



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 2, 1996

FILE COPY

Samia N. Rodriguez
Hyman, Phelps & McNamara, P.C.
Counsel for Purac America Inc.
700 Thirteenth Street, N.W.
Washington, D.C. 20005

Dear Sir:

Your petition submitted on behalf of Purac America Inc., requesting The Food and Drug Administration to amend the requirements for designation of ingredients for foods, specifically 21 C.F.R. 101.4(b), to grant an exception for the label declaration of ingredients for black olives that allows the use of language indicating that one of the color fixatives ferrous lactate and ferrous gluconate may not be present in the olives.

It was assigned docket number 96P-0230/CP 1 and it was filed on 7/02/96. Please refer to this docket number in future correspondence on this subject with the Agency.

Please Note that the acceptance of the petition for filing is a procedural matter in that it in no way reflect an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in dark ink, appearing to read "Lyle D. Jaffe".

Lyle D. Jaffe
Dockets Management Branch

96P 0230

ACK 1