October 7, 2003

6967 '03 DET 16 P1 51

Jenny Butler **Dockets Management Branch** Food and Drug Administration, Room 1061 5630 Fishers Lane Rockville, MD 20852

I have cc: this letter to several people. All of whom, have been a participant in my crusade, willingly or unwillingly. This letter is in answer to Joseph Famiglietti, Compliance Officer with FDA, regarding an entry at customs. You have somehow participated in this matter and I hope one of you will take the time to read it throughly and realize that I am not the "bad guy" here.

As I said before, FDA Regulations does not always protect the consumers. I beleive, most people I have had to deal with in this matter, have been protecting themselves rather than protecting the consumers. You be the judges!

Yours truly

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Joanne Gervais

2003P.0162

October 7, 2003

Joseph A Famiglietti, Compliance Officer U.S. Food and Drug Administration 300 Pearl St. Suite 100 Olympic Toweres Buffalo, NY 14202

Joanne Gervais JM Investment Inc 319 Third Ave. Melbourne Beach, FL 32951

Re: Entry Number 310-5362527-8

I need directions and answers. On September 25, 2003 when I spoke to you on the phone regarding this entry, I explained the extenuating circumstances surrounding my case. I will now put this on paper.

On August 26, 2003 a Notice of FDA Action was mailed to JM Investment Inc. 1414 S Federal Hwy, Dania, Fl. Because the letter was mailed to my corporation it was put aside.

On September 25, 2003, I received my mail including the above Notice of Action. When I read it I saw the name of the person I had to contact was you. I proceeded to call you for direction. You told me to look up the date on the notice I had to respond, regarding the admissibility of the articles. When I looked it up, I realized it said September 16, 2003. That day had already past. I then explained what had happenned. The business Lucky "7" Food Store was sold on July 14, 2003, the same day of the entry. The entry was held at custom for two weeks and was then allowed to enter. When it was received into the store, the new owner assumed everything was ok. They did not know or realized there was a problem with some of the articles and that they had to wait for the release from custom. This is not an excuse but they are only human. They had just purchased the business and there was so many things they had to learn that when and if a detained notice was received by them, normally by fax, it was probably put aside not realizing what the document meant.

Unfortunatly, because of these circumstances I was not made aware of it until September 25, 2003. This is when I called you. After I explained everything, you told me I had to deal with custom to clarify the matter. Now today, after trying for a week to clarify everything with custom, they tell me I have to talk to you. As I said before, all I want are directions. I don't know where to turn to anymore.

Prior to this, back in January when I spoke to you, the problem with the products was the labels. On my own, I research what could be done and on April 4th I sent a petition to the FDA Commissioner at the Department of Health and Human Services requesting an exemption. On May 14, I sent a letter with additional informations to be added to my petition. Unfortunatly the petition and the letter were dealt as separate issues. At the end of August after numerous and when I say numerous I mean dozens and dozens of phone calls to get an answer to my petition I am told that if I withdraw my petition and all they have to deal with is the letter (to me the letter and the petition were part of the same) it would expedite the matter and I could get an answer immediatly...So I did what I was told by the Department of Health and Human Services. It still took two weeks but I finally received an answer. They would not give me an exemption but under section 101.15 I could temporarily put stickers to correct the labels. Personnally. I feel I was deceived to withdraw the petition so they would not have to deal with it and all they did was answer the so called "letter" that was really part of the petition, not a separate issue. As of today I am resubmitting the petition and wait the 6 months to a year it will take them to answer it.

Back in January 2003, the labels were always the issue. After, I have done everything to correct this issue now there is a problem with an FCE #. All the companies manufacturing the can product are registered with FDA and have a FCE#. The products that are registered have labels for the US. The products I import I have to correct the labels so naturally they are not registered otherwise the labels would have already been made for the US. Some of the manufacturers have been in operation for almost a century. I don't think the way they process food to be sold in Canada is any different than the food that is made for the US!

When FDA is talking about a low acid canned food or acidified food manufacturer they are always referring to mushrooms. Yourself, back in January, explained that the process use for some vegetable can be very dangerous. No one ever said anything about gravy. Can you explained which cannned food is not a low acide canned food? Are all canned food a low acid food? Why in the above entry, item 036/001B, 038/001 and 039/001B are refused when they are 2oz package of dry powdered gravy in envelop and they are treated the same as canned food? As I said before, I need answers and directions.

I realize I don't own the store any more but I feel I owe the Snowbirds (Canadians and Americans even some from Buffalo who are use to cross the border to get these products) to help in providing a commodity at the Lucky "7" Food Store they have come to expect and appreciate. The state of Florida rely of these tourist for their economy. When I originally sent my petition it included a list with nearly one thousand signature from people who desire to continue to purchase the food they are familiar with. Isn't there voice worth anything? After all, they are the consumers.

In the mean time, the articles have been removed form the shelf in the store until further notice. Unfortunately, only what is left of them because under these extenuating circumstances I was not made aware there was a problem until now.

One last thing; on Febuary 26, I sent a letter to Angla Pope (Low Volume / Small Business Exemption Questions) after finding her name on the internet. On this letter I

which they would not qualify under the Small or Low Volume Business Exemption. How they can sell international food that is not labelled for the U.S. I asked her, "are they legal, illegal or exempt?" I got her answer over the phone which was, "They haven't got caught." Very professional answer! In the mean time, the product has a sticker with the name of the importer, the products' labels are in spanish only and the metric conversion is not corrected. Is U.S. customs in Miami different from customs at the Canadian border, or is it because they rather close there eyes to accommodate a Latino community? The issue in my petition was never addressed!

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I have enclosed my correspondance with the Department of Health and Human Services (the petition, the so called letter and their answer) also to customs prior to to the July 14 entry and all other correspondance in connection with this matter. I would appreciate an answer to all my questions.

Yours truly Anais Dofre (

Joanne Gervais

cc: Tommy Thompson, Secretary of Health and Human Services Todd Manning, FDA Supervisor, Champlain Port of Entry Felicia B. Satchell, Director of Food Labeling and Standards Jenny Butler, Dockets Management Branch, Food and Drug Administration The Small Business and Regulatory Enforcement Ombudsman Denise Paquin, Lucky "7" Food Store owner

LIST OF ALL CORRESPONDANCE PERTAINING TO THIS MATTER

Schedule 1. Febuary 26, 2003

Letter to Angela Pope re: products allowed to be sold in Miami, that do not meet FDA requirements as to proper labels, to accomodate the Latino community.

Schedule 2. April 2, 2003 Petition was mailed to FDA Commissioner.

Schedule 3. April 7, 2003 Receipt of my petition from the Department of Health and Human Services.

Schedule 4. May 13, 2003 The so-called "letter" that was part of the petition.

Schedule 5. May 14, 2003 Letter to Thommy Thompson that included the petition and the letter.

Schedule 6. June 11, 2003 Fax to custom before entry # 310-5362527-8

Schedule 7. September 2, 2003 Answer from the Department of Healh and Human Services, Which they faxed to me but never mailed it.

Schedule 8. August 22, 2003

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Letterto Jenny Buttler to withdraw my petition, under pressure from Wanda Kelker, so I could get an answer for the so-called "letter".

Schedule 1

February 26, 2003

From: Joanne Gervais Marcel Gravel Lucky "7" Food Store Dania, FL 33004

Tel # 954-923-3663 (W) 954-924-8525 (H) Fax # 954-923-8017

To: Angela Pope Low Volume / Small Business Exemption Questions

Fax # 301-436-2639

I am writing to you, as you are my last hope to save my business. The following is to brief you on what has happen in the last few months.

The business I own is a small convenience store. I am located in south Florida; an area that abounds with French Canadian tourist called "Snowbirds" as they spend their winter here. To be able to serve them better, I have been importing food products from Canada, as they are familiar with them.

For the last 5 years, FDA Agents have visited the store on a yearly basis. They always examine the food in the store, sometimes made suggestions on a matter, but their area of concern was always as long of the products had English labeling, we were in compliance. Canadian labels are both in French and in English.

The goods I carry in the store are purchase from different distributors in Montreal, then a brokerage firm codes the articles for custom and then it is shipped to us by transport. Back in November 2002, when a shipment was coming through, some items were detained at custom. One month later we received a "Notice of FDA Action". Out of 26 products 14 were detained and 12 were released. Most of the item were detained because of misbranding, i.e. the net contents listed in metric units, the labeling fails to bear the required nutrition information. FDA advised me that I had the right to provide oral or written testimony to the, to the Food & Drug Administration regarding the admissibility of the articles or the manner in which the articles can be brought into compliance. The way to do this is filling form FD 766.

After many calls to different manufacturers, I was able to collect the missing information on the labels. I proceeded to file form FD 766 providing them with copy of stickers to be applied on food products, which would show the missing information. See attached copy of FD 766 forms that were submitted. Has you will see, even items with nutritional information were denied because "Nutrition Facts" was not use. They also

refuse that I put a sticker with the sparppriate US unit conversion.

When all of this happened, I had already file a Small or Low Volume Business Exemption as I qualify but FDA said it did not include products that was not manufactured by me. I don't understand, as on the form part 3. Type of Firm, we checked Retailer & Importer, under part 6. Report of units sold, we listed on a separate sheet the name of the Product, No. of Units, Manufacturer. See attached form.

I have contacted different companies from Canada, which imports food in the US. Unfortunately, the labels have had a significant change to serve the American market but it is unknown to the Canadian Snowbirds as the nutrition information and ingredient is in English only. The format they are used to is different.

I understand FDA concern as to inform consumers but the above approach would not serve the consumers, as they are French Canadian. The Canadian Government has made it mandatory for manufacturer to include nutrition information on their labels and has given them 3 years to comply. Even after all my products have the nutrition information, the panel may not say "Nutrition Facts" which according to FDA makes it then illegal for sale in the US.

I have done some research on the Internet and have found a Government Act called RFA (Regulatory Flexibility and Enforcement Act of 1980) and SBREFA (Small Business Regulatory Fairness and Enforcement Act of 1996). The title alone of these would suggest these Acts capable of helping me to continue to provide a service to the local tourist.

To conclude this matter, today I went to this local market with millions of sales yearly, that would not qualify under the Small or Low Volume Business Exemption, who carries international foods with stickers for labels on some products, with a sticker for US unit conversions or with only foreign language on the product with no translation. See the attached photo of the products. Are they legal, illegal or exempt?

I need answers to my questions. I don't want to loose my business. I have already invested a lot of money and it has cost me a lot because of misleading information.

Desperate for advice. Joanne Gervais Marcel

Owner

Gravel Owner

04/02/03

To: FDA Commissioner, Schedule 2 Dockets Management Branch Food and Drug Administration, Room 1061 5630 Fishers Lane Rockville, MD 20852

From: Joanne Gervais & Marcel Gravel
J. M. Investments Inc. D.B.A. Lucky "7" Food Store 1414 South Federal Hwy, Dania, Florida, 33004
work # 954-923-3663
home # 954-924-8525

Re: Petition for special permission to import Canadian food products that do not meet FDA regulations for labeling. Food to be sold at the retail level only, at the Lucky "7" Food Store.

We are located in the South Florida, an area which is filled with French Canadians. More than one million Canadian "Snowbirds" contribute to South Florida's tourism economy. These Canadians are accustomed to their own products which are labeled in both English and French and safe for human consumption.

Under the "Fair Packaging and Labeling Act," chapter 39 section 1451 states, "Informed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparison. Therefore, it is hereby declared to be the policy of the congress to assist consumers and manufacturers in reaching these goals in the marketing of consumer goods."

This policy is not accomplishing its purpose, though. The French Canadian consumers are not protected since the information on the products available in this part of the US are only in English or English & Spanish.

Under chapter 39 section 1454, (b) Exemption of commodities from regulations states, "If the promulgating authority specified in this section finds that, because of the nature, form, or quantity of a particular consumer commodity, or for other good and sufficient reasons, full compliance with all the requirements otherwis**Sephecited inde**r section 1453 (Requirements of Labeling; Placement, Form, and Contents of Statement of Quantity; Supplemental Statement of Quantity) of this title is impracticable or is not necessary for the adequate protection of consumers, the Secretary or the Commission (whichever the case may be) shall promulgate regulations exempting such commodity from those requirements to the extent and under such conditions as the promulgating authority determines to be consistent with section 1451 of this title." Under chapter 39 section 1454, (b), I am asking for an exemption to section 1453.

My store is your typical little corner store you familiarized with to go and buy candies when you were a kid. Our customers are French Canadians. They are familiar with the products because they grew up with them and so did their parents and grand-parents. My consumers are not entirely Americans, and they are not protected with the American labels.

I have contacted different Canadian companies who import into the U.S. The products are made in Canada, but labeled for the American market. Again, my consumers are not protected as the labeling is in English only. Section 1451 is not being accomplish.

I know this is a special request I am asking of you, but I want to be able to give the Canadian tourists spending 3 to 6 months in Florida, this service. This area of Florida offers Canadian tourists a variety of services which is a reason why they return every year. In our area, the following services are offered in French; banking, medical clinics, hospitals, chiropractic clinics, dental clinics, real estate, accounting, lawyers, gas stations, newspapers, hair dressers, restaurants, motels, and the list goes on. Being able to accommodate them with their food is an added service to attract them in Florida and continue to contribute to the economy in this area. All these services would not be available unless their was a demand for them.

This store has been in operation for 30 years. It has been under our ownership for the last 5 years. Because it is a small business, we qualify under the "Small Business Exemption" for nutritional information, but this exemption does not exempt us from the rest of the requirements in section 1453. It also does not exempt us if a product contains nutritional information that is not in compliance with the FDA regulations. The Canadian Government has made it mandatory for Canadian companies to list nutritional information on their products. They have three years to comply. Under this exemption as soon as a product has a nutritional claim I lose my exemption and no longer can I carry it in my store. This is ironic, as soon as a Canadian product offer nutritional information for the protection of the consumer it then becomes illegal because it is not title "NUTRITION FACTS" and never will because it is not feasible for a French and English label. It will always say "NUTRITIONAL INFORMATION NUTRITIONNELLE" which accommodate much easier the French and English language.

I have enclosed copies of news paper and magazine available in the area for French Canadians. I have pulled some advertisements with English translation for your viewing. Pictures of our store so you can see that we are only a small business offering a service to the French Canadians. Also, we have gathered a petition from our customers wishing the products available in our store will still be there when they come back next winter. Without those products, we no longer have a business. All that is left is to close the store.

I hope I have convince you that the service I am offering is not offending any Americans, it is only attracting a consumer who is a major contributor to the tourism economy in this area. Laws cannot always accomplish its purpose under every situation. I don't mean any disrespect to the FDA regulations but under these circumstances they are not accomplishing their purpose for the protection of this unique consumer.

I certify, to the best of my knowledge, all the information I have provided in this petition are true. If you require additional information or material to support this petition, I will gladly forward it to you.

Respectfully, Alla Alla

cc. Todd Manning, FDA Supervisor, Champlain Port of Entry Neil Baisi, Canadian Embassy, Foreign Affair and International Trade



Schedule 3⁻

Food and Drug Administration Rockville MD 20857

April 17, 2003

Joanne Gervais & Marcel Gravel J.M. Investments, Inc. D.B.A. Lucky "7" Food Store 1414 South Federal Hwy. Dania, Florida, 33004

Dear Ms. Gervais:

Your petition requesting the Food and Drug Administration for special permission to import Canadian food products that do not meet FDA regulations for labeling, was received by this office on 04/04/03. It was assigned docket number 03P-0162/CP1 and it was filed on 04/02/03. 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 reflects an agency decision on the substantive merits of the petition.

Sincerely,

elen te Marsi

Helen K. Harris Dockets Management Branch.



Schedule 5

May 14, 2003

Tommy Thompson The U.S. Department of Health and Human Services 200 Independence Ave, S.W. Washington D.C. 20201

For your viewing, I have enclosed copies of correspondence to the Food and Drug Administration requesting a special permission to import Canadian food that do not meet FDA label regulation.

The first letter was sent on April 4, 2003, followed by a second letter on May 13, 2003.

I would greatly appreciate your comment on this matter. You can e-mail me at <u>Lucky7foodstore@aol.com</u> or by mail at 1414 S. Federal Hwy, Dania, FL 33004.

Thank You,

Joanne Gervais Aeriais e

Schedule for food store 1414 South Federal Highway Dania Beach, Fl. 33004 954-923-3663 954-923-8017 Tr FAR OANNE GERVAIS Date :_ 6- 11- 3 De / From : 🝧 MANNINA A/ To : YODD Fax No: 1-518-298.5138 No Pages :______

FLOM SOANNE GERVAIS

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Jodd, Schedule 6 I hollowed your advise and ound someone to properly label the products. I am exclosing a label for you to verify to make such It is OK also, some of the products are for restaurants. I know, if the package is for whole sale I don't have to correct the labels. One product for restaurant is the not dog burn They are not package for wholesale because this is the only packages they come in . Thave enclosed a mere of the restaurant that sells the toasted hot dog so you can new it. There is also another rectaurant who wants me to order 500 dos of hot dog burs The owner of that restaurant has a brend who works for US Custom and he will rouch for him Quill call you later this afternoon to confirm

At Dairy Belle Ice Cream, we promise you that you will always get the freshest food available and cooked when you order it. We make our own spaghetti sauce and our own caramel (old family recipe). Our Smoked 91eat is imported from Montreal and our cheese for our famous Poutine is imported from Warwick, Canada (Kingsey Cheese). We only buy the best quality food money can buy. Our family has been in the ice cream and restaurant business for many years so we know how to do it white to us at DairyBelle98@aol.com right! Should you have any questions or comments

How To find us?

We are on US1 Between Dania Beach Blvd. and Old Griffin Rd, On the East side.

Dairy Belle Ice Cream Inc, is owned and Operated by Silles & Ritane Srenier

Menu Concept was made By Francois Grenier International Concepts, Inc

DAIRY BELLE ICE CREAM



Since 1998 Nous Parlons Francais 118 N. Federal Hwy Dania Beach, FL 33004 (954) 920-3330 Prices are subject to change without notice

From our kitchen

Steamed Hotdog	
\rightarrow Toasted Hotdog (Toasted buns from Canada) 1.45	
Blt Sandwich, (bacon, lettuce, Tomato)	
Chili Dog	
Corn Dog (we use POGO brand)1.75	
Chicago Dog2.00	
Club Sandwich, all white meat (with fries & slaw)6.25	
Cheeseburger	
Club Sandwich Poutine	
Chicken Sandwich	
French FriesLarge1.75	
French Fries with GravyLarge 2.75	
Fried Chicken Sandwich2.79	
Guedille (lettuce, tomatos, onions, mix with mayo, on toasted hotdog bun)2.00	
Guedille with Chicken (all white meat)2.40	
Grilled Cheese	
Hamburge 1/4 lbs)2.49	
HamburgerSteak (with fries and grilled onions)	
Hot Chicken with fries)	
Hot Hamburger (with Fries)9.99	
Hot Hamburger Caruso (with Fries)6.50(with Poutine)10.25	
Italian Poutinelarge .7.25	
PoutíneLarge .5.99	
Michigan Dog (steamed)2.00	
Smoked Meat Sandwich (with fries and pickle)	
Spaghetti with meat sauce (with Garlic Bread)Small4.50Large5.95	
Tomato Sandwich (toasted)2.25	
Onion Rings (In Beer Batter)2.00	
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Extras

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Chili	0.50
GrilledOnions	0.25
Cheese (yellow American)	0.25
Smoked (Meat meat only)	
Make your Burger a BLT, add	

Cole Slaw	0.30
Gravy	0.80
Extra Cheese (for poutíne)	1.25
Cabbage (raw)	0.25
Coke, Diet Coke, Sprite,Orange1.	05 1.25
Bottle of Water	0.90
Coffee	0.90
Can of Soda	1.25
Juice	1.50

Ice Cream

Soft Ice cream (Cone or Cup)	1.451.952.25	
Milkshakes		
Sundae		
Banana Split		
Strawberry Short cake		
Blizzard (Oreo, M&M,Resses, Heath bar, Snickers, Butter Finger)small2.55		
	large3.00	
Floats		
Ice Cream Soda		
Chocolate Dip		
Waffle Cone		
Sprinkles		
Peanuts		
M&M		
Whipped Cream		
Banana		



DEPARTMENT OF HEALTH AND HUMAN SERVICES



T-918 P 02/02 F-425 Public Health Service

Food and Drug Administration College Park, Maryland

Schedule 7

SEP 2 2003

Joanne Gervais & Marcel Gravel J.M. Investments, Inc. D.B.A. Lucky "7" Food Store 1414 South Federal Highway Dania, Florida 33004

Dear Ms. Gervais:

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This responds to your May 14, 2003 letter requesting special permission from the Food and Drug Administration (FDA) to import Canadian food products that do not meet FDA labeling regulations.

We can appreciate your concern about the continued availability of products that make up the inventory of your retail store. However, we regret that FDA can not give you special permission to import food that does not meet the United States (U.S.) labeling regulations. While FDA cannot give you special permission we note that under Title 21 of the Code of Federal Regulations section 101.15 products distributed in the U.S. may bear labeling in both English and a foreign language provided all information required by U.S. food labeling regulations appears in both languages. You may be able to temporarily accomplish this through sticker labeling while you try to locate a manufacturer/distributor who will offer products specific to your business needs. However, these product labels cannot bear nutrition information in the Canadian format because this information is not in compliance with the U.S. nutrition labeling requirements.

Sincerely yours,

Felicia B. Satchell Director Division of Food Labeling and Standards Office of Nutritional Products, Labeling and Dictary Supplements

To: Warda Kelker 301-436-268 FROM: JOANNE Gervais Lucky 7 FOOD STORE Here is the letter that was sent to Jerry Blitler to withdraw my petition. ··· · · · · · · · ···· ··· · · • • • · . • • . **. .** · . and and a second se ÷....

08/22/03

To: Jenny Butler Schedule 8 Dockets Management Branch Food and Drug Administration, Room 1061 5630 Fishers Lane Rockville, MD 20852

From: Joanne Gervais & Marcel Gravel J.M. Investments Inc. D.B.A. Lucky "7" Food Store 1414 South Federal Hwy. Dania, Florida, 33004 work # (954) 275-3293 home # (321) 724-1329

Re: Docket Number 03P-0162/CPI

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With this letter, take notice that I wish to withdraw my petition submitted 04/02/03 docket number 03P-0162/CPI.

At the time this petition was filled, I was unaware of the right procedure that should have been taken. A letter to the Food Labeling Administration was sufficient and the petition was not necessary.

Could you please notify Wanda Kelker at the Food Labeling Administration 301-436-2371 of my decision to withdraw this petition.

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Yours Truly,

Joanne Gervais