



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Tifton, GA Resident Post
P.O. Box 1709
Tifton, GA 31794

MEMORANDUM

Date: 2/13/04

From: Janet B. Gray, CSO
Tifton, GA RP

Subject: Follow-up for Complaint # 22892

To: Blake Bevill, SI
Atlanta, GA DO

On 1/28/04, I was notified by my supervisor, Blake Bevill, to conduct a follow-up investigation for a consumer complaint that was received by the KAN-DO on 1/12/04. The complaint involved an 18 oz. plastic jar of Reduced Fat Crunchy Peter Pan Peanut Butter that had reportedly had a misprint on the nutritional labeling for the correct amount or percentage of carbohydrates. See ATTACHMENT A for a copy of the Consumer Complaint Report. The complainant, Ms. (b)(4) noticed on a container of reduced fat peanut butter that she had purchased from (b)(4) in located in (b)(4) the nutritional labeling stated 5 grams of carbohydrates per 2 tablespoons instead of the normal 14 grams of carbohydrates. The manufacturer of the product is ConAgra Foods, Inc., 101 S. Seabrook Dr., P.O. Box 585, Sylvester, GA 31791. The lot code on the product was "S32202311D".

On 1/30/04, I contacted Ms. (b)(4) and ask for details concerning her complaint. Ms. (b)(4) said that she is a diabetic, and she has been controlling her diabetes by restricting the amount of carbohydrates in her daily diet. She said that the low-carbohydrate diet was recommended by her dietician and she has been on the regime since November of 2003. She says that she has been able to control her diabetes and since she has been on the diet she has not had to take insulin. She said that she has lost 15 lbs. since November. Ms. (b)(4) informed me that since she is on a low-carbohydrate diet, she reads all nutritional labels for everything she eats, so that she will not go over her recommended intake of 195 grams or less of carbohydrates each day. She said that she routinely purchases reduced fat peanut butter, and she is aware of the normal amount of carbohydrates per serving. She said that she had just purchased a new jar of reduced fat crunchy peanut butter and she noticed that the nutritional label stated 5 grams of carbohydrates instead of the usual 14 grams of carbohydrates per 2 tablespoons. She said that she was concerned because there might be other people that are on a low carbohydrate diet for health reasons and she didn't want someone to over-do it thinking that they were getting fewer carbohydrates than they actually were. She said that she called the phone # listed on the jar for comments, and she talked to a man that looked up the lot code # for the peanut butter on a computer, and he said that their computer showed that the nutritional label listed that the product had 15 grams of carbohydrates. Ms. (b)(4) told the man that she was looking right at her jar and it said 5 grams. The man said that he would look into it. Ms. (b)(4) said that several days later, a woman from Peter Pan left a message on her answering machine, stating that there was a misprint with the labels and it had been taken care of. Ms. (b)(4) added that she had recently received some coupons and a letter from the manufacturer stating that the problem with the mislabeling had been corrected and that the label should have read 14 grams not 5 grams.

Ms. (b)(4) said that on 1/10/04 while shopping at the same (b)(4) she noticed that the labels on the Peter Pan Reduced Fat Peanut Butter still had 5 grams of carbohydrates instead 14 grams. At this time, she decided to notify FDA. Ms. (b)(4) stated that she didn't know if the lot codes were the same. Ms. (b)(4) said that she didn't know the specific dates or names of the representatives from Peter Pan that she had talked. Ms. (b)(4) said that she went back to the same store again on 1/24/04 and she looked through all of the jars and didn't find any declaring 5 grams. She said that they now said 15 grams and that it appeared that they had gone up a gram. Ms. (b)(4) felt that the misbranded amount of carbohydrates could throw off her diet and other people that had to watch their carbohydrate intake. I thanked Ms. (b)(4) for her concerns and time, and told her that there would be a follow-up investigation at the manufacturer.

On 2/3/04, I visited ConAgra Foods, Inc. located in Sylvester, GA. Credentials were presented to and the FDA-482, Notice of Inspection, was issued to Mr. Selvin L. Smith, Plant Manager, and the most responsible individual for the operations at the firm, see ATTACHMENT B. Mr. Michael Matis, QC Manager, was also present during the initiation of the inspection. I explained that the purpose of my visit was to follow-up on a consumer complaint that we had received concerning a misprint for the amount of carbohydrates per serving on their Reduced Fat Crunchy Peter Pan Peanut Butter. Mr. Matis immediately knew what I was referring to and he told me that they had been notified and the problem had been corrected. He said that they were notified by their corporate office in Irvine, California on 1/7/04. Mr. Matis stated that he wasn't sure where the consumer got the 14 grams from because the product had always had 15 grams. Additionally, Mr. Matis said that he thought that the product involved was their (b)(4) brand not Peter Pan. He said that they

were never told why there was a misprint, but they had pulled all of the labels that had the incorrect carbohydrate amount on the label. He said that all of the old labels were in his office. Ms. Matis stated that the printing of labels as well as the label review are handled by their corporate office. He said that they do a cursory label review for the correct weights, product name, brand name, and kosher symbol. He said that they do not review the nutritional label. Mr. Matis showed me the misprinted labels that were pulled and kept in his office. He also took me to the label and packaging storage area to show me that all of the labels stating 5 grams had been removed. I observed that all of the labels present for reduced fat peanut butter stated 15 grams of carbohydrates. Mr. Matis ask what the lot code was on the consumers jar and I told him that it was "S32202311 (D or O)". He said that the last letter was a D because they do not use O in their coding system. Mr. Matis explained that they had developed a new coding system since the last inspection. He said that the S is for Sylvester; 3 is for the year; 220 is for the julian date; 2311 is for the time of packaging; and D is for the production line. Mr. Matis said that this particular lot was produced on 8/8/03. At this time, Mr. Matis checked to see if they still had any of this product on hand, but he said that all of this particular lot had already been shipped. He said that he was not surprised because they usually ship the product out shortly after production.

A closing discussion was held with Mr. Smith and Mr. Matis. Management said they had not received any more complaints to this nature that they were aware of. Mr. Matis said that all complaints or comments were handled by their home office located in Omaha, Nebraska. Mr. Matis said that they did not issue a recall or product removal because they didn't feel that it was a health risk, and since the product was produced in August they felt that there was probably just a small amount of product under this lot code in distribution. Management informed me if I had any other questions concerning when and how the complaint was received that I should call Dave Navarrette, Director of Regulatory Affairs, who is located in Irvine, CA. I was also informed that I would have to issue a written request for information before I would be able to get any information from their corporate office. I thanked them for their time and cooperation and concluded the inspection.

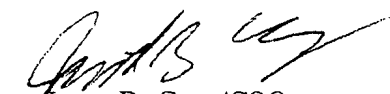
While at the firm, I collected sample #254933 consisting of 12/28 oz. plastic jars of Peter Pan Creamy Peanut Butter for aflatoxin analysis as per FY' 04 mycotoxin surveillance assignment. ATTACHMENT C is a copy of the collection report for the above sample. The FDA-484, Receipt for Samples, was issued to Mr. Michael Matis, see ATTACHMENT D.

ATTACHMENT A: Consumer Complaint Injury Report; 3 pages

ATTACHMENT B: Notice of Inspection; 1 page

ATTACHMENT C: Collection Report for Sample # 254933; 3 pages

ATTACHMENT D: Receipt for Samples; 1 page


Janet B. Gray/CSO
Tifton RP