

Kelker, Wanda K

From: Whitmore, George
Sent: Wednesday, March 03, 2004 8:55 AM
To: Kelker, Wanda K
Cc: Satchell, Felicia B
Subject: Industry inquiry on low carb products

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Hello Wanda,

Here below is our latest industry inquiry on low-carb claims, for your response.

Many thanks,
 Arthur Whitmore
 Industry Staff/OCO/CFSAN
 301-436-1706

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

From: Heather Hines [mailto:heather@lowcarbcreations.com]
Sent: Tuesday, March 02, 2004 8:15 PM
To: CFSAN-OCO3
Subject: validated protocols for testing of low carb products

I hope you can help me. I am on a quest for assistance regarding the current confusion involving the nutritional analysis of low carb food items.

Dateline NBC recently released a report on low carb food nutritional labels that conflicted with the nutritional labels produced by their independent labs. Our company, Low Carb Creations, elected to have five separate independent food labs test all of our products. All five labs came back with conflicting nutritional labels from one another. We inquired about these differences, and learned the labs are not all using the same "theoretical values" to test various ingredients. Sugar alcohols, fibers and the actual measurement for carbs are all at issue, in addition to other ingredient tests that evidently vary from lab to lab and batch to batch.

What this leaves the low carb food industry is an inconsistent way of listing nutritional values, and therefore a lack of confidence from the consumer, that they can expect any nutritional label to be accurate. We understand the limitations of the labs with regard to the NLEA, but we are trying to identify if there is anything that can be done to develop some consistency or a way to clarify for both retailers and consumers.

We are wondering if, during the interim period until FDA can establish and rule on a standardized test protocol, there is any possibility of the FDA providing a guideline for the food analysis labs to use to assist them in testing low carb foods with some consistency. Otherwise, it is highly likely anytime the media (or anyone else) decides to have an independent lab analyze a low carb food product for nutritional content, the report will not necessarily match the label. We are very proud of our products but we want to be honest about the current limitations while retaining consumer confidence in labeling. We do not expect FDA to produce an overnight ruling to establish an industry standard for "low carb". We are hoping for a solution that will restore confidence that nutritional labels have any credence at all.

We will be at the Expo West Trade Show in Anaheim this weekend (March 5-7) and we will hand out a statement regarding the current issue. We would be very grateful if your department can provide any recommendation of information we can provide for our customers.

Thank you for your time and assistance in this matter.

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Sincerely,
Heather Hines
Low Carb Creations