

# ATTORNEY GENERAL'S COPY

## 1. Noticing Individual

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Phone No. 818-402-2203

2. TO: Bioenergy, Inc., 13840 Johnston St. NE Ham Lake, MN 55304, Clarence Johnson, Ph.D., C.E.O. and Stephen Sinatra, M.D. 257 East Center Street, Manchester, CT 06040

3. Time of occurrence 1998 until present

4. RE: Acrylamide

5. Route of exposure as per Section 25249.6 of the Act is by ingestion.

## DESCRIPTION OF VIOLATION

### FORMATION OF ACRYLAMIDE BY COOKING WITH D-RIBOSE

The primary recipient of this notification, Bioenergy, Inc., started the production and marketing of the pentose sugar D-ribose by declaring to the FDA that it was a common sugar found in every cell of the body so not dangerous, without revealing the fact that it is not a simple natural sugar inside the body but rather a compound so can be even more dangerous if used improperly.

Although allowing production and marketing, the FDA refused to grant the substance GRAS status. Even so, Bioenergy continued to market D-ribose without notice to the public that it was not to be cooked with. Even though ribose compounds inside meat are recognized as flavor enhancers even at relatively low temperatures, now we know that this is an unavoidable source of acrylamide. To start marketing this very unstable synthesized crystalline product without warning that it is not to be cooked with, even though it is a flavor enhancer when so used, is extremely negligent and not to have informed the FDA that warning labels to avoid cooking with ribose are needed, Bioenergy failed to disclose and induced Stephen Sinatra, M.D. to write a book, "The Sinatra Solution" without disclaimers. Because Bioenergy has shown total disregard in protecting the public, which is evidence of its indifference, facts must be cited so that it can disagree if it believes inaccuracies are being disclosed, whereby it can provide its own differing laboratory proof to the State, of caramelization point and subjecting the sugar to one mole (18 grams) of water per one mole (150 grams) of powdered D-ribose.

Pursuant to Section 8 of the Dietary Supplement Health and Education Act of 1994, it would appear that even though D-ribose has been used in the laboratory as a reagent, not a food, since the turn of the 20<sup>th</sup> century, and it has only been proposed to be used as a food 3 years after the 1994 act became law, while the FDA did not have the immediate obligation to differentiate it from ordinary food, the promoters of it certainly did and they failed. Was it deliberate? Johnson being a Ph.D. certainly should have known.

Rpt 21	alpha-D(-) ribofuranose (ribose)	Humanetics Corporation	10/28/97	Filed without comment
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The lead statement in this Report-21 is what the notifier especially takes exception to:

“Dear Dr. Kahl:

Pursuant to Section 8 of the Dietary Supplement Health and Education Act of 1994, Humanetics Corporation, on its own behalf and on behalf of Bioenergy, Inc., Minneapolis, Minnesota, wishes to notify the Food and Drug Administration that it will market a new dietary ingredient, alpha-D(-) Ribofuranose (Ribose), a naturally-occurring simple sugar found in all foods. Accordingly, enclosed are two (2) copies of this notification. The dietary supplement that contains Ribose will consist of up to five (5) grams of Ribose in liquid or capsule form for ingestion which will be suggested to be taken two to four times per day.”

Even at that time Humanetics and Bioenergy knew that ribose was not a *naturally-occurring simple sugar found in all foods*. It is a compound. The designation of simple sugar implies that it is like its precursor in the body, glucose. Ribose does not exist free in nature, and these marketers did not want to bring up this “can of worms” to alert the FDA that it was not, because this would represent a delay, possibly requiring a new drug application. Therefore, they masqueraded it as a simple sugar so as to be able to lump it in with natural occurring foods and so deceived the FDA. The Dietary Supplement Health and Education Act of 1994, besides safety considerations, requires a *descriptive name of the product*. In the case of ribose, a descriptive name requires to say what it becomes immediately upon being placed in the mouth as the synthetic sugar it is. Once discovering the true nature of D-ribose, notifier informed Bioenergy and others, but Bioenergy refused even to consider the issue. Now he is even more concerned because of the undisclosed cooking danger. While ribose is not yet a household name, other than because of its association with DNA, it is being widely sold over the Internet as accessing Yahoo and Google would indicate. Ribose is doing what it does naturally, forming compounds. It is no accident that glucose in the free-state must be converted to a compound (glucose-6-phosphate) before it can form ribose (ribose-5-phosphate) as a compound. That is why ribose is the sugar of life, but it is too reactive to use in cooking and warning labels are needed. It cannot exist in the free-state in the human body and is immediately converted to a compound in the mouth, its monohydrate. Therefore nobody consumes D-ribose as a simple sugar, and regulators need to address this issue before it gets out of hand, and people use ribose to make a delicious cooked food in part because of its hypoglycemic nature. There are people already doing this, and the public must be warned not to do so by the potential danger of cooking with it being put as a warning on the label.

What they have failed to do was disclose what ribose exactly is and does. This begins the problem. The people who were planning to market it originally did not choose to report it themselves but rather hired a surrogate, Ronald Zenk of Humanetics, with

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whom notifier has spoken. He admitted that he had done no independent testing of D-ribose but depended on information furnished by Clarence Johnson of Bioenergy, who apparently did not want to submit this information himself although he was the one who was going to market it, and Ron Zenk had no such intention. Had Mr. Zenk even took some of this substance and performed a few tests incumbent upon something being marketed as a simple sugar, he would have noticed that this was not a simple sugar. Although it has been reported to melt at  $\pm 85^{\circ}\text{C}$ , it actually melts at  $\pm 65^{\circ}\text{C}$  and quickly begins to caramelize. Caramelization means the sugar is oxidizing and turning brown. Oxidizing means that new substances are forming, some likely being mutagenic, including acrylamide.

In 2002 two divergent things happened, 1) the Swedes discovered that acrylamide was a danger to the food supply, and the FDA disclosed that ribose produced acrylamide, while 2) Bioenergy asked for GRAS approval for a new food additive, ribose, that can be used with meat and poultry without disclosing that it was not safe to be cooked with meat and poultry. Meat and poultry are not eaten raw.

The GRAS notification was GRAS Notice No. GRN 000100, and the FDA disclosure from the FOOD ADVISORY COMMITTEE February 24 - 25, 2003 Meeting on Acrylamide

*Transcript of Proceedings February 24, 2003*

as it pertains to ribose is as follows:

“Are there other carbonyl sources that can form acrylamide? Some recent work speculated that the formation of acrylamide from asparagine, the structured degradation reaction--structured degradation reaction is implicitly explained, actually a di-carbonyl such as, in this case, glyoxal reacting with the amino acid causes the reaction to proceed. We also showed that glyceraldehyde, 2-deoxyglucose and ribose are also efficient at forming acrylamide in food systems.

“People who are familiar with the Maillard reaction understand that the typical browning reaction involves first a reaction of a carbonyl amino acid. If you use a molecule such as 2-deoxyglucose where it is C2 here, you do not have a hydroxyl group. This prevents the molecule from undergoing the rearrangement. So, this actually lets us know that all we need is to Schiff base the formation for the formation of acrylamide. This is also verified by reactions we did, lipid aldehyde such as decanal, and Dr. Adam Bakowsky at Health Canada also published about octynal, another lipid aldehyde that can react with asparagine to form acrylamide.

“However, people may ask is lipid oxidation contributing to acrylamide formation? I would think not because if you look in the food system, typically the reducing sugars are probably on the order of about one to two magnitudes higher than the lipid aldehydes. So, I think what we need to be concerned with is level of reducing sugars.”

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**Notice that while they exonerate 2-deoxyglucose, they do not do likewise with ribose, and of course sugars themselves are not exonerated, but glucose (dextrose) is an ordinary time-honored food that only forms this potential carcinogen at 160° C. Ribose starts 100 degrees lower. It is important that the truth be told to protect the public of long term risks, even though warning labels are not welcomed by manufacturers. It is very important as the ribose market increases due to its ability to improve diastole in congestive heart failure and its possible benefit in type II diabetes that people realize it should not be used in cooking even though it can make good tasting upscale food for the affluent.**

**Therefore, the marketers and promoters of D-ribose powder need to put a disclaimer on the packaging that D-ribose powder is not to be used in cooking either by itself or with poultry and meat products as well as dairy and grains.**

**Attachments:**

**Certificate of Merit**

**FDA GRAS Notice No. GRN 000100 with address of U.S. FDA**

**FDA FOOD ADVISORY COMMITTEE February 24 - 25, 2003 Meeting on Acrylamide, Transcript of Proceedings February 24, 2003, noted in text above, same address as the GRAS notification**

**The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)**

**A COPY OF THIS NOTICE IS BEING PROVIDED TO:**

**THE ATTORNEY GENERAL OF THE STATE OF CALIFORNIA**

**THE DISTRICT ATTORNEY OF LOS ANGELES COUNTY**

**THE CITY ATTORNEY OF THE CITY OF LOS ANGELES**

CERTIFICATE OF MERIT

Health and Safety Code Section 25249.7(d)

KEITH E. KENYON MD

I, (name of certifier), hereby declare:

(1) This Certificate of Merit accompanies the attached sixty-day notice(s) in which it is alleged the parties identified in the notices have violated Health and Safety Code section 25249.6 by failing to provide clear and reasonable warnings.

(2) I am the (noticing party/attorney for the noticing party).

(3) I have consulted with one or more persons with relevant and appropriate experience or expertise who has reviewed facts, studies, or other data regarding the alleged exposure to the listed chemical that is the subject of the action.

(4) Based on the information obtained through those consultations, and on all other information in my possession, I believe there is a reasonable and meritorious case for the private action. I understand that "reasonable and meritorious case for the private action" means that the information provides a credible basis that all elements of the plaintiffs' case can be established and the information did not prove that the alleged violator will be able to establish any of the affirmative defenses set forth in the statute.

(5) The copy of this Certificate of Merit served on the Attorney General attaches to it factual information sufficient to establish the basis for this certificate, including the information identified in Health and Safety Code section 25249.7(h)(2), i.e., (1) the identity of the persons consulted with and relied on by the certifier, and (2) the facts, studies, or other data reviewed by those persons.

Dated: 08/31/05

Keith E. Kenyon MD  
(Signature)