

From: Mark Gold [mgold@shelltown.net]  
Sent: Sunday, January 12, 2003 11:08 PM  
To: fdadockets@oc.fda.gov  
Subject: Docket # 02P-0317 Recall Aspartame as a Neurotoxic Drug: File #1

Subject: Docket # 02P-0317

To: FDA Dockets Submittal

From: Mark D. Gold  
Aspartame Toxicity Information Center  
12 East Side Dr., Suite 2-18  
Concord, NH 03301  
603-225-2110

Date: January 12, 2002

Please find below Evidence File #1: Summary

Aspartame Summary

-----

I am familiar with the world research on aspartame toxicity and speak regularly with independent scientists around the world on the issue.

I would like to clear up a few issues related to the aspartame issue. The evidence related to toxicity of aspartame is found primarily in three areas:

1. Formaldehyde Exposure. The formaldehyde exposure from aspartame is significant. Aspartame breaks down into methanol, amino acids and several other chemicals. The methanol is quickly absorbed and converted into formaldehyde. The methanol found in foods and alcoholic beverages is also absorbed, but there are "protective chemicals" in these traditionally-ingested foods and beverages that prevent the conversion of methanol to formaldehyde.

Formaldehyde is known to cause gradual damage to the nervous system, the immune system and has recently been shown to cause irreversible genetic damage at long-term, low-level exposure.

The most recent, independent research shows that the situation related to aspartame may be more serious than simply regular formaldehyde exposure. This research on animals demonstrates that the formaldehyde appears to accumulate as adducts (bound to protein molecules) in the organs and tissues of the animals (when aspartame is ingested at relatively low doses):

"These are indeed extremely high levels for adducts of formaldehyde, a substance responsible for chronic deleterious effects that has also been considered carcinogenic.

....

"It is concluded that aspartame consumption may constitute a

hazard because of its contribution to the formation of formaldehyde adducts."

[Life Sciences (scientific journal), Vol. 63, No. 5, pp. 337+, 1998]

A comment from an independent research scientist regarding this and other recent aspartame research:

"It was a very interesting paper, that demonstrates that formaldehyde formation from aspartame ingestion is very common and does indeed accumulate within the cell, reacting with cellular proteins (mostly enzymes) and DNA (both mitochondrial and nuclear). The fact that it accumulates with each dose, indicates grave consequences among those who consume diet drinks and foodstuffs on a daily basis."

[Russell Blaylock, MD [Neurosurgeon and Neuroscientist]

The calculated level of formaldehyde exposure is approximately 61.3 mg (milligrams) for every liter of aspartame ingested. That is over twice the level necessary to cause irreversible genetic damage in humans and several times the level shown to cause chronic neurological, cardiovascular, musculoskeletal, and other symptoms in long-term industrial exposure research.

The damage caused by formaldehyde from aspartame may be worsened by other aspartame breakdown chemicals, especially the aspartic acid. In animal research where formaldehyde is given to the animals to cause damage and pain, amino acids such as aspartic acid and glutamic acid are given at the same time to worsen the reaction. The amino acids from aspartame are absorbed suddenly unlike the protein-bound amino acids found in food.

2. Independent research finds problems with aspartame. An analysis of peer

reviewed medical literature using MEDLINE and other databases was conducted by Ralph G. Walton, MD, Chairman, The Center for Behavioral Medicine, Professor of Clinical Psychiatry, Northeastern Ohio Universities College of Medicine. Dr. Walton analyzed 164 studies

which

were felt to have relevance to human safety questions. Of the 90 non-industry-sponsored (independent) studies, 83 (92%) identified one or more problems with aspartame. Of the 74 aspartame industry-

sponsored

studies, all 74 (100%) claimed that no problems were found with aspartame.

3. Extremely large number of reported toxicity reactions to aspartame.

As of 1995 when the U.S. Food and Drug Administration (FDA) was quoted as saying they stopped accepting adverse reaction reports on aspartame,

over 75% of the adverse reactions reported to the FDA Adverse Reaction Monitoring System (ARMS) were due to aspartame. After considering the

fact that an extremely low percentage of adverse reactions are reported to the FDA, it becomes clear that there are millions of known cases of aspartame toxicity reactions and possibly many other cases where the person ingesting aspartame is either 1) unaware that their symptoms are caused or contributed to by aspartame; or 2) not yet experiencing clinically-obvious symptoms from the breakdown products of aspartame, but may eventually experience chronic health problems from the regular exposure to significant doses of formaldehyde.

Some of the many aspartame toxicity symptoms reported include seizures, headaches, memory loss, tremors, convulsions, vision loss, nausea, dizziness, confusion, depression, irritability, anxiety attacks, personality changes, heart palpitations, chest pains, skin diseases, loss of blood sugar control, arthritic symptoms, weight gain (in some cases), fluid retention, excessive thirst or urination. Clearly, regular exposure to a toxic substance such as formaldehyde may worsen, or in some cases contribute to the development of chronic diseases.

I would be glad to share scientific information with independent researchers and physicians who are interested in the subject of aspartame toxicity. Independent, referenced scientific information for researchers and physicians can be found in the Scientific Section of the following Internet web page:

<http://www.holisticmed.com/aspartame/>

Here are some further resources:

Scientific Files

<http://www.holisticmed.com/aspartame/abuse/>

<http://www.holisticmed.com/aspartame/aspfaq.html>

Detox document

<http://www.holisticmed.com/aspartame/detox.html>

Aspartame Poisoning Case Histories

<http://www.holisticmed.com/aspartame/adverse.txt>

<http://www.holisticmed.com/aspartame/adverse2.txt>

Healthier Sweetener Resource Center

<http://www.holisticmed.com/sweet/>

Offsite Resources:

The following web page:

<http://nancymarkle.com/doctors.html>

contains a recent article published in "The Ecologist" magazine as well as articles and statements by the following independent researchers and

physicians:

- Dr. Russell Blaylock
- Dr. H.J. Roberts
- Dr. James Bowen
- Dr. Sandra Cabot
- Dr. Miles E. Drake
- Dr. Louis Elsas
- Dr. James B. Hayes
- Dr. Virgil M. Hulse
- Dr. Cristine Lydon
- Dr. Woodrow C. Monte
- Dr. John Olney
- Dr. Madelon Price
- Dr. Morgan Raiford
- Dr. Richard J. Sabetes
- Dr. Charles Schwartz
- Dr. Peter A. Simkin
- Dr. Ralph Walton
- Dr. Julian Whitaker
- Dr. George M. Wolverton

Keep in mind that *\*none\** of the physicians and researchers listed above have accepted money from the manufacturer or any competing interest. Most of them have read the key research related to aspartame at the time they wrote their views.

Here is a TV Show interview about aspartame (Real Audio):

Part 1

<http://www.newviewtv.com/channel6.ram>

Part 2

<http://www.newviewtv.com/sweetp2no1.ram>

A link to the most recent European study showing that aspartame ingestion in animals at relatively low doses (10 mg/kg) causes the accumulation of formaldehyde in the liver, kidneys, brain, and other tissues.

<http://www.PRESIDIOTEX.COM/barcelona/>

For more information about the level of formaldehyde exposure from aspartame, please see: <http://www.holisticmed.com/aspartame/fm.html>

Case history of physician suffering from aspartame poisoning:

<http://www.holisticmed.com/arthritis/>

Dr. Ralph Walton, MD's preliminary review showing nearly all independent research has found problems with aspartame:

<http://www.dorway.com/peerrev.html>

Dr. Janet Starr Hull - Creator of the Aspartame Detoxification Program

<http://www.sweetpoison.com/>

Dr. Lendon Smith's excellent article on aspartame:

<http://www.dorway.com/lsmith.html>

Testimony of FDA Scientists/Investigators (not government 'officials')

<http://www.dorway.com/betty/fdainves.txt>

<http://www.dorway.com/gross.txt>

<http://www.dorway.com/bressler.txt>

Along these lines, here is an important article from the Minnesota Star Tribune about government officials and aspartame research :

<http://www.dorway.com/startrib.html>

(Note: web page addresses ending in ".ram" need Real Audio software. Most computers have it. It can be obtained for free from [www.realaudio.com](http://www.realaudio.com))

1. Fox News Broadcast on Aspartame  
<http://www.aspartame.com/ram/foxstory.ram>
2. Recent article by Christine Lydon, MD  
<http://www.aspartame.com/lydon.htm>
3. Real Audio Radio Interivew with Neuroscientist Russell Blaylock, MD  
<http://www.aspartame.com/ram/mpr060398.ram>

Transcript of Broadcast  
<http://www.aspartame.com/blaylock.htm>

4. Position Paper by Sandra Cabot, MD  
<http://aspartame.com/aspartam.htm>
5. Interview with James Turner, a Consumer Attorney involved with the issue since the early 1970s.  
<http://www.aspartame.com/ram/mpr040898.ram>

Transcript of Broadcast  
<http://aspartamekills.com/jimturner.htm>

=====

Mark Gold  
Aspartame Toxicity Information Center  
12 East Side Dr., #2-18

Concord, NH 03301

603-225-2110

mgold@holisticmed.com

<http://www.HolisticMed.com/aspartame/>