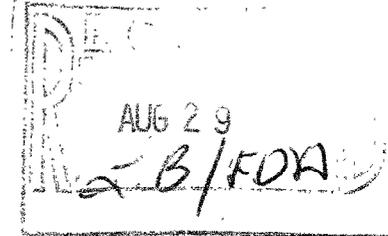




August 24, 2005

VIA FEDERAL EXPRESS

ONPLDS/CFSAN/FDA
College Park, MD



Subject: Pre-market Notification for New Dietary Ingredient

To Whom It May Concern:

Enclosed please find Albion's submission of Manganese GlucosamineTM for pre-market notification. Please contact me if you have any questions.

Sincerely,

ALBION ADVANCED NUTRITION

A handwritten signature in black ink, appearing to read "Brent M. Burningham".

Brent M. Burningham
General Counsel

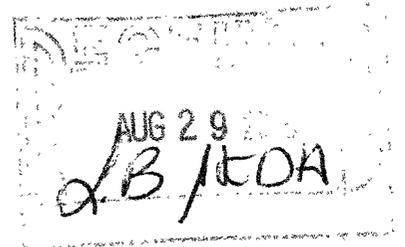
Enclosure

2005-5547
AIMS

PRE-MARKET NOTIFICATION FOR NEW DIETARY
INGREDIENT

MANGANESE GLUCOSAMINE GLUCONATE
(hereinafter "Manganese GlucosamineTM")

In accordance with CFR 190.6(a)



Albion Laboratories, Inc. d.b.a. Albion Advanced Nutrition
101 North Main Street
Clearfield, UT 84015

24 August 2005

Pre-Market Notification for New Dietary Ingredient

1. The name and complete address of the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient¹:

Albion Laboratories, Inc. d.b.a. Albion Advanced Nutrition
101 North Main Street
Clearfield, UT 84015

2. The name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical:

Manganese Glucosamine Gluconate (hereinafter "Manganese GlucosamineTM")

3. A description of the dietary supplement or dietary supplements that contain the new dietary ingredient including:

(i) The level of the new dietary ingredient in the dietary supplement.

Daily Dosage: 100mg of Manganese GlucosamineTM delivers the RDA dose of 5mg of manganese and a dose of 43mg of glucosamine.

(ii) The conditions of use recommended or suggested in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the labeling of the dietary supplement, the ordinary conditions of use of the supplement.

The ordinary conditions of use for Manganese GlucosamineTM include oral supplementation in typical dosage forms as a supplement to other sources of manganese and glucosamine in the diet. When administered in the Daily Dosage stated above, consistent with the manganese RDA, additional glucosamine from other generally accepted sources can be co-administered to raise the glucosamine dosage level to levels more typical for glucosamine supplementation.

Alternatively, Manganese GlucosamineTM can be dosed at levels targeting the adult DRI upper limit of 11mg of manganese. A daily dose of 220mg of Manganese GlucosamineTM delivers the adult DRI upper limit dose of 11mg of manganese and 95mg of glucosamine, thus reducing the amount of additional glucosamine supplementation required from other sources.

4. The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer of the

¹ Numbered paragraphs and italicized text correspond to requirements stated in CFR 190.6(a).

dietary supplement that contains the new dietary ingredient has concluded that the new dietary supplement will reasonably be expected to be safe. Any reference to published information offered in support of the notification shall be accompanied by reprints or photostatic copies of such references. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation.

Safe use of the constituents of Manganese Glucosamine™ is well documented. In fact, because there are few, if any, known harmful effects of manganese ingestion at high doses, manganese products are currently on the market with doses of 40mg and 50mg of manganese. Glucosamine is administered at doses of one to one and one-half grams (1-1.5g). Thus, both main constituents are routinely available in doses many times higher than the doses proposed with Manganese Glucosamine™. Nevertheless, we are proposing a more conservative manganese dose in this new dietary ingredient consistent with the upper limit DRI for adults of 11mg. Relevant pharmacopeial citations and publications concerning the constituents or otherwise relevant to the conclusion that Manganese Glucosamine™ is reasonably expected to be safe are listed in Appendix A, and full text copies are included with this submission as Appendix B.

5. *Why has it been concluded that the NDI is a “dietary ingredient” under the definition specified in DSHEA.*

DSHEA identifies the following as dietary ingredients:

“(A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E) . . .”

Manganese Glucosamine™ is a dietary ingredient under (F) in that it is a combination of (B) minerals and (E) other dietary substances for use by man to supplement the diet.

6. *Chemical characterization of NDI.*

Melting Point	(165°F)
Decomposition Point	(221°F)
Flash Point	(None)
Flammability	(None)
Solubility	(Freely soluble 1g/10mL H ₂ O)
pH	5
Description:	An odorless powder that is white-tanish in color

The complete Manganese Glucosamine™ product specification sheet and MSDS are attached as Appendix C.

7. *The composition or formulation of the dietary supplement containing the NDI.*

Manganese Glucosamine™ is intended for administration as one ingredient in a multi-ingredient supplement, the formulations of which will vary by dietary supplement manufacturer. In addition, Manganese Glucosamine™ may be administered alone. The confidential composition of Manganese Glucosamine™, on an anhydrous basis, is included as Appendix D to this Notification. The product specifications and MSDS for the starting materials of Manganese Glucosamine™, also confidential, are included as Appendix E.

8. *Safety documentation that clearly describes the scientific reasoning used by Albion in concluding that the data provided establishes a reasonable expectation of safety.*

In addition to the references available concerning the safety of ingredients of Manganese Glucosamine™, Manganese Glucosamine™ was the subject of a toxic category determination study. Excerpts from the report are included below:

2000 mg/kg: All six animals survived the 2000 mg/kg oral dose in good health. Body weight changes and necropsy results were normal.

5000 mg/kg: All three female animals died within twenty-four hours of the 5000 mg/kg oral dose. Predeath physical signs included lethargy ataxia, dyspnea, flaccid muscle tone, prostrate, wet and soiled anogenital area piloerection, diarrhea coma and depressed body temperature. Necropsy revealed moderate liver mottling in two animals; pronounced fluid distention and moderate redness of the stomachs of all three animals; moderate fluid distention of the intestines of all three of the female animals with moderate intestinal red areas in two females and less incidence of intestinal redness in the third female, but with moderate incidence of yellow areas on the intestines of the third female. This same female showed slight soiling and moderate wetness of the anogenital area.

Conclusion: Manganese Glucosamine™ Gluconate, Lot/batch #6324802 is considered to be in Acute Toxic Category 5. The LD is less than 5000 mg/kg but greater than 2000 mg/kg.

The full text of the confidential LD report is attached as Exhibit F.

CONCLUSION

As noted above, the manganese RDA based dosing level; 100 mg of Manganese Glucosamine™ would deliver 5 mg of manganese and 43 mg of glucosamine. At the adult DRI upper level based dose for manganese, 220mg of Manganese Glucosamine™ would deliver 11mg of manganese

and 95mg of glucosamine. Based on its review of the relevant literature concerning use of manganese, glucosamine and other starting materials of Manganese Glucosamine™, and further based on the findings of the toxic category study of this new dietary ingredient, Albion has concluded that Manganese Glucosamine™ is safe when administered in the range of doses calculated to satisfy either the RDA or at the adult DRI upper level for manganese.

9. *The signature of the person designated by the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient.*

ALBION ADVANCED NUTRITION



Stephen Ashmead
Vice President Research & Development