DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: JAN 23 2002

From: Consumer Safety Officer, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-821

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

04 16 '03 JAN 27 P2:11

Subject of the Notification:	zinc carnosine
Firm:	Lonza, Inc.
Date Received by FDA:	May 28, 2002
90-Day Date:	August 26, 2002

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Rhonda R. Kane, M.S., R.D.

Attachments

95S-0316

RPT 134

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

July 23, 2002

W. Patrick Noonan
Warner Center Plaza, Suite 840
21800 Oxnard Street
Woodland Hills, California 91367

Dear Mr. Noonan:

This is to inform you that the notification and amendment, dated May 13, 2002 and May 28, 2002 respectively, you submitted on behalf of your client Lonza, Inc. pursuant to 21 U.S.C. 350b(a)(2) were received and filed by the Food and Drug Administration (FDA) on May 28, 2002. Your notification concerns the substance called "zinc carnosine" that you assert is a new dietary ingredient.

The notification explains that Lonza, Inc. would serve as the distributor of zinc carnosine that would be manufactured by Yonezawa Hamari Chemicals, Ltd. for use as a source of zinc in dietary supplements containing other ingredients such as vitamins and minerals. The notification further states that the intended target population of consumers of zinc carnosine is adults, excluding pregnant and lactating women, and children older than 12 years of age. The recommended level of intake of zinc carnosine noted in the notification is 75 mg per day, which would deliver approximately 17 mg of zinc, a mineral, and 58 mg of L-carnosine, a dipeptide.

In accordance with 21 C.F.R 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date (i.e., until after August 11, 2002), your client must not introduce or deliver for introduction zinc carnosine into interstate commerce for use as a dietary ingredient in any dietary supplement.

Please note that acceptance of this notification for filing is a procedural matter and does not constitute a finding by the FDA that zinc carnosine or a dietary supplement containing it is safe or is not adulterated under 21 U.S.C. 342. Further, FDA is not precluded from taking action in the future against any dietary supplement containing zinc carnosine if it is found to be unsafe, adulterated or misbranded.

As another procedural matter, your notification will be kept confidential for 90 days after the filing date. Therefore, after August 26, 2002, the notification, its amendment and related correspondence from you and FDA will be placed on public display at FDA's Dockets Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information that is in the notification will not be disclosed to the public.

We acknowledge your request to withhold from public disclosure certain information in the notification that your client identified as being proprietary because it addresses the test methods for zinc carnosine. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets.

For your client's future reference, the FDA Internet site http://www.cfsan.fda.gov/~dms/ds-labl.html#structure provides details on the types of claims that are allowed for dietary supplements, including structure/function, health and nutrient content claims. Federal regulations at 21 CFR 101.36 address the general labeling requirements of all dietary supplements whether or not claims are made.

For claims that are allowed under 21 U.S.C. 343(r)(6) (e.g., those related to the structure or function of the human body or one's general well-being), a dietary supplement's labeling must include a specific disclaimer. In addition, no later than 30 days post marketing, the product's manufacturer or distributor must notify FDA in writing about a structure/function claim. Federal regulations at 21 CFR 101.93 specify the notification requirements for such claims. Label claim notification requirements are separate from those for the new dietary ingredient premarket notification program.

FTC Internet site http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm provides details on Federal requirements concerning the advertising of dietary supplements. All dietary supplement claims made in both product labeling and advertising must be substantiated with scientific evidence, be truthful, and not be misleading.

Please contact me at (301) 436-2371, if you have any questions concerning this matter.

Sincerely yours,

Rhonda R. Kane

Rhonda R. Kane, M.S., R.D.
Consumer Safety Officer
Dietary Supplements Team
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

LAW OFFICES

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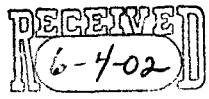
TELECOPIER (818) 887-7099

May 30, 2002



Ms. Rhonda R. Kane
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling,
and Dietary Supplements (HFS-821)
Food And Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

Re: New Dietary Ingredient Notification: Zinc Carnosine

Dear Ms. Kane:

As you requested, enclosed are the two additional copies of the pre-market notification for the new dietary ingredient zinc carnosine. We have amended the pre-market notification to incorporate the changes in our May 28, 2002 letter and are providing you copies of the amended pages. Please amend the original and two copies of the prior three filings as follows:

1. Replace Table of Contents page 1;

2. Replace Section One;

3. Replace Section Two; and

4. Replace Section Five.

Also included are the original and two copies of the letter sent to you via facsimile dated May 29, 2002.

Sincerely,

W. Patrick Noonan

WPN/mw
Enclosures
cc: Dan Murray
Lonza, Inc.

TABLE OF CONTENTS

SECTION ONE

Names and complete addresses of the distributor and the manufactuer of the new dietary ingredient. See 21 CFR § 190.6(b)(i).

The distributor of zinc carnosine is:

Lonza, Inc.
17-17 Route 208
Fair Lawn, New Jersey 07410

Contact: Mr. Dan Murray
Associate Director, Technical Development,
Nutrition Sales and Marketing
(678) 445-3535 phone
(678) 445-3611 fax
e-mail: dmurray2@lonza-us.com

The manufacturer of zinc carnosine is:

Yonezawa Hamari Chemicals, Ltd.
2-4300-18, Hachimanpara
Yonezawa, Yamagata 922-1128
Japan

Contact: Iwao Shimizu, Ph.D.
Director Quality and Technology Department

SECTION TWO

Name of the new dietary ingredient that is subject of the pre-market notification. See 21 CFR § 190.6(b)(2).

The new dietary ingredient is identified as Zinc Carnosine.

The CAS number for zinc carnosine is 107667-60-7.

SECTION FIVE

The conditions of use recommended or suggested in the labeling of the dietary supplement. See 21 CFR § 190.6(b)(3)(ii).

The distributor of zinc carnosine will recommend the use of the dietary ingredient zinc carnosine as a new source of zinc for use in the manufacturing of dietary supplement products that are offered and marketed to supplement the human daily diet with zinc and other nutrients.

The targeted population for the dietary ingredient zinc carnosine is adults including children over the age of twelve. [1]

Zinc carnosine will be recommended as an additional dietary source of zinc for inclusion in multivitamin, mineral, and other dietary supplements offered daily with no limitation on duration of use.

Zinc carnosine will be recommended for adults only and will not be intended for use by pregnant or lactating women.

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[1] See Section 411(a)(2) of FDC Act, defining "children" as individuals under the age of twelve years.

LAW OFFICES

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TELEPHONE (818) 887-5600
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May 29, 2002

Via Facsimile and Federal Express

Ms. Rhonda R. Kane
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling,
and Dietary Supplements (HFS-820)
Food And Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

Re: New Dietary Ingredient Notification: Zinc Carnosine

Dear Ms. Kane:

This clarifies our conversation today that Lonza, Inc. pursuant to 21 CFR § 20.61 requires that only the "test methods" found in Section Three, Attachment A (last two pages) be considered confidential information. This confirms also that two additional copies of the above submission will be sent to FDA by the end of this week. If you should have any questions concerning this matter, please contact me immediately.

Sincerely,

W. Patrick Noonan

WPN/mw
cc: Dan Murray
Lonza, Inc.

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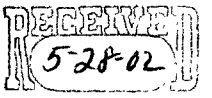
May 28, 2002



Via Facsimile and Federal Express

Ms. Rhonda R. Kane
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling,
and Dietary Supplements (HFS-820)
Food And Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

Re: New Dietary Ingredient Notification: Zinc Carnosine

Dear Ms. Kane:

In accordance with our recent conversation, Lonza, Inc. is pleased to provide the Food and Drug Administration (FDA) with the following additional information.

1) Amend Section Five of the above new dietary ingredient submission identified as "conditions of use recommended or suggested in the labeling of the dietary supplement" to include;

   a) The targeted population for the dietary ingredient zinc carnosine is adults including children over the age of twelve. [1]

   b) Zinc carnosine will be recommended as an additional dietary source of zinc for inclusion in multivitamin, mineral, and other dietary supplements offered daily with no limitation on duration of use.

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[1] See Section 411(a)(2) of FDC Act, defining "children" as individuals under the age of twelve years.

c) Zinc carnosine will be recommended for adults only and will not be intended for use by pregnant or lactating women.

2) The CAS number for zinc carnosine is 107667-60-7.

3) The manufacturer of zinc carnosine is:

Yonezawa Hamari Chemicals, Ltd.
2-4300-18, Hachimanpara
Yonezawa, Yamagata 922-1128
Japan

Contact person:
Iwao Shimizu, Ph.D., Director Quality and Technology Department

4) Lonza, Inc. will assist FDA in reviewing this new dietary submission by providing via Federal Express two additional copies of the zinc carnosine new dietary supplement submission dated May 13, 2002.

We will further amend the Table of Contents in those additional copies to reflect that Section One indicates the name and address of the distributor of the new dietary supplement.

We understand that with submission of the above information, FDA will initiate review of the zinc carnosine new dietary ingredient submission and therefore establish the initial date for the 75 day pre-market notification. If FDA should require any additional information concerning the Lonza, Inc. submission for zinc carnosine, please contact me immediately.

Sincerely,

W. Patrick Noonan

WPN/mw
Enclosures
cc: Dan Murray
Lonza, Inc.

LAW OFFICES

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May 13, 2002

Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling,
and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food And Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

Re: New Dietary Ingredient Notification: Zinc Carnosine

Dear Sir or Madam:

Enclosed please find an original and two copies of the 75 day pre-market notification for the dietary ingredient zinc carnosine as required by Section 413(a)(2) of the Food, Drug, and Cosmetic Act (FDC Act) and a regulation issued by the Food and Drug Administration (FDA) at 21 CFR § 190.6.

Please note that pursuant to 21 CFR § 20.61, we request that Section 3 product specification and test methods be considered confidential information.

Zinc carnosine in powder form will be offered as a new dietary source of zinc for the dietary supplementation of zinc in the daily diet. Zinc is one of the recognized trace minerals essential for human nutrition. Carnosine is a dipeptide consisting of beta-alanine and histidine as its component amino acids. It is present mainly in the skeletal muscles of mammals and humans. The submission contains a table of contents that will allow quick reference to the submitted material and scientific studies.

We appreciate your attention to this submission. If you should have any questions regarding the notification, please contact me.

Sincerely,

W. Patrick Noonan

WPN/mw
wp\42\zinccarnosine

Enclosures

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May 13, 2002

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Center for Food Safety and Applied Nutrition
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5100 Paint Branch Parkway
College Park, Maryland 20740-3835

Re: New Dietary Ingredient Notification: Zinc Carnosine

Dear Sir or Madam:

Enclosed please find an original and two copies of the pre-market notification for the new dietary ingredient zinc carnosine.

Sincerely,

W. Patrick Noonan

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WPN/mw

Enclosures