



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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Dear Stakeholders:

Today, we are placing 34 documents in docket 95S-0316 (see enclosure 1). This action eliminates a backlog of new dietary ingredient notifications made to the agency pursuant to 21 U.S.C. 350b(a) (section 413(a) of the Federal Food, Drug, and Cosmetic Act) and 21 CFR 190.6 that we were not able to place on public display in a timely fashion. We have implemented procedures in the center for Food Safety and Applied Nutrition (CFSAN) that will enable us to more efficiently manage this type of notification and ensure that we meet the disclosure requirements of the Act in a timely fashion in the future.

If you have any questions regarding the documents placed in docket 95S-0316 today, please contact CFSAN's Office of Nutritional Products, Labeling and Dietary Supplements at 301-436-2373.

Sincerely yours,

Christine J. Taylor, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Enclosure

95S-0316

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Attachment 1. List of New Dietary Ingredient Notifications Placed in Docket 95S-0316

<u>RPT</u>	<u>New Dietary Ingredient</u>	<u>Firm</u>
124	Yomoa Powder (Funtumia elastica)	The Remedy Co., Inc.
125	Extract of natto (nattokinase)	Lane Labs-USA
126	Healthy Respiration	Am. Res. Inst. Of Word Traditional Medicine
127	Lactobacillus delbrueckii	Pure Research Products Naturally
128	Iron-Aid	Chemi Nutraceuticals, Inc.
129	Ganoderma lucidum Spore Powder	Herbs Generation Intl., Ltd.
130	HiDHA tuna Oil	Clover Corp., LTD
131	Neptune Krill Oil (Krill oil extract)	Neptune Technolgies & Bioresources
132	Neptune Aquateine (Krill dry Fraction) Powder	Neptune Technolgies & Bioresources
133	Neptune Lyo-Krill (freeze dried Krill)	Neptune Technolgies & Bioresources
134	Zinc carnosine	Lonza, Inc.
135	Desmodium adscendens	Biodynamics Nv
136	Cordyceps sinensis mycelia, cultured	Homegi Biotech Intl. Corp.
137	Momordica charantia L.	Trinity International, LLC
138	Cordyceps sinensis mycelia	Premiere Towa, Inc.
139	Sheep placenta	Yat Chau (USA), Inc.
140	EPA/DHA (ginseng fish oil)	Yat Chau (USA), Inc.
141	EPA/DHA (omega-3 fish oil)	Yat Chau (USA), Inc.
142	Egg lecithin	Belovo, Inc.

<u>RPT</u>	<u>New Dietary Ingredient</u>	<u>Firm</u>
143	Liquid Gold Root Extract	Phytos, Inc.
144	Lactobacillus delbrueckii	Pure Research Products Naturally
145	Neptune Krill Euphausia (Krill Aquateine/Lyo-Krill)	Neptune Technolgies & Bioresources
146	N-acetylserotonin (normelatonin)	Heartmind Nutrition
147	Echium plantagineum seed oil	Pharmax LLC
148	7-keo-DHEA	Perrigo Company
149	Pueraria mirifica	Triarco Industries
150	Luteolin (tetrahydroxyflavone)	SYNORX, Inc.
151	Oculax	Yat Chau (USA), Inc.
152	Golden Phoenix	Hounghwa Global, Inc.
153	Uridine	AMINO GmbH
154	Creatine ethyl ester (Cre-ester)	Pro-nutrient Technologies, Inc.
155	Ganaderma lucidum	Gano Excel (USA), Inc.
156	Geranti Bio-Ge	Geranti Pharm Ltd.
CR-1	Hirudo powder	Wealth Express Industrial, Ltd.