

February 24, 2020

Via e-mail: steven.tave@fda.hhs.gov

Steven J. Tave
Director
Food and Drug Administration
Office of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition
5001 Campus Dr.
College Park, MD 20740

Re: Request for Immediate Enforcement Action to Stop Adulterated Forms of Beta-Alanine from Being Imported Into the U.S.

Dear Mr. Tave:

We are writing on behalf of Natural Alternatives International, Inc. (NAI), to follow-up on our prior meetings with the Food and Drug Administration (FDA or Agency) and reiterate NAI's request that FDA take swift and appropriate enforcement action against companies that are importing adulterated beta-alanine into the United States in clear violation of the Federal Food, Drug & Cosmetic Act ("FD&C Act"). The laws of the United States do not allow for such willful disregard for public safety. NAI respectfully requests that FDA issue an Import Alert ("IA") to stop adulterated generic forms of beta-alanine from entering the U.S.¹ It has become imperative that FDA take this action to protect the public health, as well as the integrity of its own laws and regulations as provided by the FD&C Act for dietary supplements and dietary ingredients. This action will not only serve public interests, but also protect responsible dietary supplement brand owners that invest the resources necessary to submit a NDIN to FDA.

NAI is a publicly-traded company and the sole importer and distributor of beta-alanine sold under the well-known and respected brand name, CarnoSyn[®] beta-alanine. In November 2018, NAI submitted a New Dietary Ingredient Notification (NDIN) to FDA for CarnoSyn[®] beta-alanine, to which it received an acknowledgement letter without objections (AKL letter) from FDA on

¹ NAI's request for an IA is a proposed action that it believes FDA could take to stop a verified, widespread violation of the FD&C Act at the border, while minimizing the burden on Agency resources. It is not meant to be viewed as the only action FDA could take regarding this issue. If the Agency believes an import bulletin is a more effective action, then NAI would, of course, be supportive of FDA's decision and provide any further information necessary.

February 1, 2019.² (See Attachment A, AKL letter for NDIN #1103). As described during meetings at FDA in 2019 and in further detail below, NAI diligently monitors import records and has identified millions of kilograms of adulterated, generic forms of beta-alanine being imported into the United States from companies in China that blatantly refuse to submit an NDIN and comply with U.S. laws. These entities instead choose to use various unidentified and potentially harmful methods of manufacturing to produce large quantities of generic forms of beta-alanine that are subsequently imported into the U.S., used in the manufacture of dietary supplements and sold to American consumers. NAI respectfully submits that it presents an undeniable case for enforcement by FDA that is straightforward, consistent with U.S. laws and regulations, does not overburden agency resources and will result in the best interest of American consumers.

Background

Under Section 201(ff)(1) of the FD&C Act, a dietary ingredient is any one of the following: (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 (A), (B), (C), (D), or (E). A New Dietary Ingredient (“NDI”) is defined as a dietary ingredient that was not marketed in the United States (U.S.) before October 15, 1994 (21 U.S.C. § 350b(d)). Under Section 413 of the FD&C Act (21 U.S.C. § 350b), a dietary supplement that contains a NDI shall be deemed adulterated under section 402(f) of the FD&C Act (21 U.S.C. § 342(f)) unless it meets one of two requirements:

1. the dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or
2. there is a 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 and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the FDA with information (in the form of an NDIN), including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. [See Section 413 of the FD&C Act (21 U.S.C. § 350b) and section 402(f) of the FD&C Act (21 U.S.C. § 342(f)).

A NDIN submitted to the Agency must contain detailed and specific information related to the safety and identity of the product. *See FDA Final Rule, Premarket Notification for a New*

² To date, NAI’s CarnoSyn® beta-alanine is the only beta-alanine for which the statutorily required NDIN has been submitted, and as such, is the only form of beta-alanine that is compliant with the FD&C Act. NAI also owns and maintains a worldwide intellectual property portfolio related to its CarnoSyn® beta-alanine that includes patents, trademarks and copyrights.

Dietary Ingredient, 62 Fed. Reg. 49886 (Sept. 23, 1997). ***If a manufacturer fails to submit the required NDIN to the FDA, a dietary supplement containing a NDI is deemed to be adulterated under Section 402(f).***

NAI is the only company that has submitted a NDIN for beta-alanine to FDA.³ NAI's notification was extensive. The company spent hundreds of thousands of dollars to not only compile publically available information about the ingredient's identity, manufacturing process and safety, but also to conduct its own commercially confidential, pre-clinical studies. The Agency did not object to NAI's basis for concluding that CarnoSyn[®] beta-alanine is reasonably expected to be safe, as manufactured, and under the conditions of use proposed in the notification.

NAI's NDIN for CarnoSyn[®] beta-alanine included information and data concerning NAI's ingredient manufacturer, Yuki Gosei Kogyo Co., Ltd. ("YGK"), located in Japan. The safety and identity data relied upon in NAI's NDIN was based on that specific manufacturer's method of production and final product of commerce. NAI only imports CarnoSyn[®] beta-alanine from YGK.

Importation of Beta-Alanine into the United States

NAI procures and imports CarnoSyn[®] beta-alanine for sale to its customers, including other contract manufacturers and branded dietary supplement companies. No third parties are authorized by NAI to rely on its NDIN, unless they purchase CarnoSyn[®] beta-alanine from the company.

NAI previously informed FDA that substantial amounts of generic beta-alanine continue to be manufactured in China and imported into the U.S., for use as a dietary supplement or a component of a dietary supplement. NAI has gathered data that shows 3,362,622 kilograms of beta-alanine were imported from February 1, 2019 through January 31, 2020. Of this total, NAI imported 1,049,412 kilograms (31% of total beta-alanine imports) from Japan and the remaining 2,313,210 kilograms (69% of total beta-alanine imports) were imported from China by other companies.⁴ Thus, the majority of beta-alanine coming into this country is generic and does not rely on a NDIN, and as such is adulterated under Section 402(f). (*See Attachment B, List of companies importing adulterated, generic beta-alanine into the United States from China*).

None of the companies importing and selling generic beta-alanine made in China can rely on NAI's NDIN # 1103, nor have they made the statutorily required pre-market notification. Thus, there is no way to determine how, or if, the ingredients being imported into the U.S. and distributed as generic beta-alanine are quantitatively or qualitatively related to CarnoSyn[®] beta-alanine—the only beta-alanine for which the required notification has been made. Because of this, FDA cannot

³ See The FDA's List of Submitted 75-Day Premarket Notifications for New Dietary Ingredients, available at <https://www.fda.gov/food/new-dietary-ingredients-ndi-notification-process/submitted-75-day-premarket-notifications-new-dietary-ingredients>.

⁴ Import data for Chinese beta-alanine imports was retrieved from PIERS TI, a well-known, third-party import database.

assume that the basis for concluding that NAI's CarnoSyn® beta-alanine is reasonably expected to be safe can be directly applied or assumed for any of the generic forms of beta-alanine.

Risks to Public Health

There are numerous inherent and unnecessary risks to the public health by continuing to allow the use of generic beta-alanine in dietary supplements. Manufacturers and distributors are knowingly evading important federal laws and regulations by denying FDA its statutorily mandated opportunity to evaluate the identity and production methods for these generic forms of beta-alanine. Without the required NDIN submissions, there is absolutely no way—short of for-cause-inspections of each of these manufacturing facilities in China—for FDA to know if any of the generic forms of beta-alanine are manufactured in a manner that does not also produce dangerous contaminants or impurities. In fact, NAI has obtained information that some manufacturers and distributors that import generic forms of beta-alanine into the U.S. utilize manufacturing processes very different from the one utilized by Yuki Gosei, NAI's Japanese manufacturer of beta-alanine. This is concerning because the manufacturing process utilized by NAI's manufacturer is the only one that FDA has had the opportunity to evaluate and determine whether it will produce a product of commerce reasonably expected to be safe under the proposed conditions of use. Instead, by violating the FD&C Act, companies refusing to submit NDINs intentionally place FDA in the untenable position of being unable to (i) know the identity and manufacturing process for any generic beta-alanine being imported into the U.S. from China, (ii) assess and prevent risks to the public health, and (iii) immediately address any health emergency that may arise.

As the Agency expressly noted throughout its 2016 draft guidance on NDINs, varying manufacturing practices may affect the purity of a food substance, introduce contaminants, and alter the physicochemical structure or biological properties, such as bioavailability or toxicity.⁵ Through investigation, NAI is aware that there are several different methods used in China to manufacture generic beta-alanine. One or more of those methods appears to include the use of genetically modified organisms ("GMOs") to synthesize the ingredient. As FDA is well aware, a manufacturing process that utilizes GMOs may cause or increase potential risks for creating contaminants and/or impurities – or worse. Refusal by manufacturers to provide this information to FDA as required in a NDIN is indicative of a potential health risk.

The FDA need go no further than the well-known L-Tryptophan crisis in 1989, to see the similarity for unnecessary public harm. In that case, FDA took action to limit the availability of dietary supplements containing the amino acid L-Tryptophan "because of the association between dietary supplements containing L-Tryptophan and the 1989 epidemic outbreak of eosinophilia-

⁵ See generally, The FDA's Draft Guidance entitled "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry" (August 2016), available at <https://www.fda.gov/media/99538/download>

myalgia syndrome (EMS) in the United States.”⁶ Epidemiological studies conducted following the outbreak revealed that 95% of the cases could be traced to one L-Tryptophan supplier.⁷ In 1988, that supplier of the L-Tryptophan dietary supplements made changes in manufacturing protocols and produced L-Tryptophan through a fermentation process using a new genetically modified strain of a bacteria. It was later shown that changes to the manufacturing protocols made by this firm resulted in the production of many impurities that were not found in L-Tryptophan manufactured using previously established protocols. One of these contaminants, a dimer of the amino acid L-Tryptophan, was strongly related to the outbreak of EMS. NAI knows that similar, but slightly different, means of production for beta-alanine can result in the presence of both characterized and uncharacterized contaminants. In fact, NAI knows that one of the contaminants characterized can be a dimer of beta-alanine. It should be pointed out that, like tryptophan, beta-alanine is an amino acid and it is possible that a dimer of beta-alanine may have toxicities similar to those of other amino acid dimers.

The use of GMOs in the L-Tryptophan case illustrates that a change or difference in the manufacturing process can alter a product and result in serious injury to consumers. The NDIN process is designed to provide FDA an opportunity to review the adequacy of the manufacturing process and the manufacturer’s conclusion that said process produces a safe NDI. Simply put, without appropriate NDIN submissions for the various forms of generic beta-alanine and outlining the associated manufacturing processes, the FDA cannot evaluate the risk of using dietary supplements containing this or any other NDI. Moreover, FDA will not have a record on file about the NDI in the event a safety problem does arise and the Agency needs to identify the root cause of the problem.

Import Alerts as a NDIN Enforcement Tool

The purpose of an import alert is to (i) prevent potentially violative products from being distributed in the United States, (ii) free-up agency resources to examine other shipments, (iii) provide uniform coverage across the country, and (iv) place the responsibility back on the importer to ensure that the products being imported into the United States are in compliance with the FDA’s laws and regulations. NAI’s request satisfies all of the criteria the FDA considers when issuing an IA. Given the wide range of risks to the public health that could result from imported ingredients that are adulterated, an opportunity to enforce the NDIN requirement at the border through issuance of an IA would have an exponential impact in preventing such dietary ingredients from making their way into domestic commerce, while freeing up agency resources to address other issues.

It is estimated that approximately 77% of Americans take dietary supplement regularly.⁸ With many, if not most, dietary ingredients being imported from other countries. As noted by you

⁶ See FDA’s Information Paper on L-Tryptophan and 5-hydroxy-L-tryptophan (February 2001), available at <http://www.nemsn.org/Articles/FDA-Info.pdf>

⁷ *Id.*

⁸ See CRN’s Press Release, entitled “Dietary Supplement Use Reaches All Time High,” Available-for-purchase consumer survey reaffirms the vital role supplementation plays in the lives of most Americans,”

at the May 16, 2019, Responsible Innovation in Dietary Supplements Public Meeting hosted by FDA, the dietary supplement industry has experienced remarkable growth since the passage of the Dietary Supplement Health and Education Act (DSHEA) in 1994. Then Acting Commissioner Sharpless stated that the industry has grown to include an estimated 80,000 products with the industry estimated to be worth over \$40 billion dollars.⁹ The frequency of unscrupulous companies exporting violative ‘copycat’ ingredients to the U.S. is likely significant, presenting a concerning, yet controllable, risk to the public health. Companies that knowingly violate the FD&C Act should not be allowed to benefit from marketing products in U.S. commerce at the expense of diligent companies such as NAI.

NAI respectfully requests that the FDA issue an IA effective to stop importation of violative ingredients by those entities breaking U.S. laws for economic gain and to avoid FDA regulations. An effective IA would serve as an effective enforcement tool to encourage companies to submit statutorily required NDINs to the Agency. Considering that the NDIN process is essentially the Agency’s only real opportunity to evaluate the safety of a NDI before it becomes widely available to consumers, an opportunity to strategically enforce the FD&C Act by issuing an IA while encouraging companies to make required NDIN submissions, should not be overlooked. Moreover, an IA is an effective enforcement tool that does not require significant resources for the Agency to enforce once it is established.¹⁰

Despite being a responsible stakeholder in the dietary supplement industry for over 40 years, since receiving its AKL letter from FDA, NAI continues to be negatively impacted by scofflaws exporting adulterated, generic forms of beta-alanine to the U.S. and FDA’s lack of enforcement of NDIN requirements. However, NAI recognizes that for FDA enforcement to be effective, it will also need to bear some of the burden and provide FDA with the necessary information to allow the Agency to take immediate action. To that end, we are providing FDA, not only with information on NAI’s NDIN, but also identification of the specific companies manufacturing and importing adulterated generic forms of beta-alanine into the United States.

available at <https://www.crnusa.org/newsroom/dietary-supplement-use-reaches-all-time-high-available-purchase-consumer-survey-reaffirms>

⁹ See Speech by Norman E. “Ned” Sharpless, MD at the FDA Public Meeting on Responsible Innovation in Dietary Supplements (May 16 2019), available at <https://www.fda.gov/news-events/speeches-fda-officials/fda-public-meeting-responsible-innovation-dietary-supplements-05162019>

¹⁰ This is particularly true here. NAI’s CarnoSyn[®] beta-alanine is made in Japan by YGK using the same manufacturer and method disclosed in NDIN # 1103. Generic forms of beta-alanine made in China and imported into the U.S. is not covered by any NDIN and is adulterated.

NAI respectfully submits that the following information should be sufficient to facilitate FDA's prompt issuance of an appropriate IA without imposing significant burden on Agency resources:

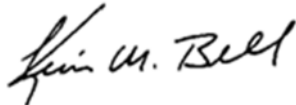
1. NAI submitted the statutorily required NDIN for CarnoSyn® beta-alanine on November 20, 2018. NAI's NDIN was assigned NDIN #1103 by FDA.
2. NAI received an AKL letter from the Agency dated February 1, 2019. (*See Attachment A*).
3. To date, there are no other NDIN's for beta-alanine on FDA's List of Submitted 75-Day Premarket Notifications for New Dietary Ingredients. (*See fn. 3*).
4. There are no third parties authorized to rely on NAI's CarnoSyn® beta-alanine NDIN.
5. List of the companies that are exporting generic beta-alanine from China, and the amounts exported into the country by these companies. (*See Attachment B*).

Conclusion

NAI is currently the only company that has submitted a NDIN for beta-alanine. Therefore, NAI or its authorized agents are the only entities allowed to import and distribute beta-alanine without violating the FD&C Act. However, the majority of beta-alanine being imported into the U.S. from China is from companies that have not submitted the required NDIN. FDA must take action to not only enforce the NDIN requirements set forth by the FD&C Act, but also to protect consumers and reputable dietary supplement manufacturers and distributors, such as NAI, that are committed to complying with all applicable laws and regulations. NAI respectfully reiterates its request that FDA issue an IA to keep adulterated, generic forms of beta-alanine out of the country and domestic commerce. NAI believes this type of enforcement action will be highly effective and may lead other reputable companies to submit the required NDINs. It will also ensure that American consumers are exposed to new dietary ingredients that have been shown to be safe.

Please let me know if there is any additional information we can provide the agency that would be useful.

Respectfully submitted,



Kevin M. Bell
Counsel for Natural Alternatives International, Inc.

Attachments

cc: Douglas Stearn
William Correll
Scott McIntyre
Cara Welch, Ph.D.

ATTACHMENT A



FDA U.S. FOOD & DRUG
ADMINISTRATION

Mr. Kevin Bell
Porzio, Bromberg & Newman
1200 New Hampshire Ave. NW, Suite 710
Washington, DC 20036-6827

FEB 01 2019

Dear Mr. Bell:

This letter is to inform you that the Food and Drug Administration (FDA) filed your notification that you submitted to FDA on behalf of Natural Alternatives International, Inc., pursuant to 21 United States Code (U.S.C.) § 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)), on November 20, 2018. Your notification concerns a new dietary ingredient that you call “CarnoSyn® Beta-alanine” that you intend to market as a bulk dietary supplement ingredient.

According to your notification, the “[r]ecommended directions for daily use are using one to two tablets of CARNOSYN® Beta-alanine (i.e. 800 mg to 1.6 g/serving) taken four times daily (maximum CARNOSYN® Beta-alanine daily intake of 6.4 g per day) following meals with water. This dietary ingredient is not intended to be used in children or pregnant women. It is intended to be used in adults (less 18 years of age). Total daily intake of 6.4 g per day [of CARNOSYN® Beta-alanine].”

Under 21 U.S.C. § 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. § 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the condition recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. § 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

In accordance with 21 CFR 190.6 (c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, your client must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains the new dietary ingredient that is the subject of this notification. Please note that acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. § 342. FDA is not precluded from taking action in the future against any dietary supplement containing your new dietary ingredient if it is found to be unsafe, adulterated, or misbranded.

U.S. Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
www.fda.gov

Your notification will be kept confidential for 90 days after the filing date of November 20, 2018. After the 90-day date, the notification will be placed on public display at www.regulations.gov as new dietary ingredient notification report number 1103. Prior to that date, you may wish to identify in writing specifically what information you believe is trade secret or confidential commercial information and include an explanation of the basis for this belief.

If you have any questions concerning this matter please contact Dr. Fred Hines, Consumer Safety Officer, Evaluation and Research Staff, at (240) 402-1756 or by email: Fred.Hines@fda.hhs.gov.

Sincerely,

A handwritten signature in black ink that reads "Robert Durkin". The signature is written in a cursive style with a large, prominent "R" and "D".

Robert J. Durkin, Esq., M.S., R.Ph.
Deputy Director
Office of Dietary Supplement Programs
Center for Food Safety
and Applied Nutrition

ATTACHMENT B

BETA ALANINE CHINESE MANUFACTURERS / EXPORTERS LIST
02/01/19 - 01/31/20

COMPANY	HQ Address	Website	TOTAL KILOGRAMS EXPORTED TO THE U.S. (1)	TOTAL # OF SHIPMENTS EXPORTED TO THE U.S. (1)	NOTES
Imports Brought In Under Confidential Status			634,774	35	Various unknown companies.
Anqing Xinfu Chemical Co., Ltd.	Phoenix Cyclic Economic Industrial Park Anqing, Anhui, Cina (Import record address) No.44, Wanhe Avenue, Daguan District Anqing, Anhui, 246005 (D&B address)	No company website found.	502,935	23	Can't confirm address.
Anhui Huaheng Bioengineering Co., Ltd.	No.32 Fengjin Road, Shuang Feng Industry Park, Hefei, Anhui, China	http://huahengbio.com/en/AboutUs/1039/1141.html	306,000	14	Address Confirmed.
Jing Jing Phramceutical Co., Ltd.	No. 88, Jingyi Road Dacaozhuang Management District, Ningjin County, Xingtai, 055550 China	http://www.hbjingjing.cn/about/show.php?id=96&lang=en	273,840	15	Address Confirmed.
Suzhou Vitajoy Bio Technology Company	B13-102,NO.192 Tinglan Lane, SIP, Suzhou, China	http://www.vitajoy-biotech.com/	232,753	10	Address Confirmed.
Xinfa Pharmaceutical Co. Ltd.	No.1, Tongxing Rd., Kenli County, Dongying, Shandong, 257599, China	http://www.sdxinfa.cn/	69,690	4	Address Confirmed.
Nanjing Shining Import and Export	#8 906, Jinlun International Plaza Hanzhong Road Nanjing, China	No company website found.	39,960	2	Can't confirm address.
Zhangjiagang Chuangyuan Plastic Industry Co. Ltd.	Shuanglong Village, Fenghuang Town, Zhangjiagang, Jiangsu, China 215614	No company website found.	36,193	2	Can't confirm address.
Sichuan Tongsheng Amino Acid	Room 1-11-1, No. 19 of North Tianshan Road, Deyang, SiChuan, China 618000	http://www.aminoacid.cc/contact_en.html	27,560	2	Address Confirmed.
Shanghai Chemspace Co., Ltd.	Building B3, 218 Huashen Road, Shanghai, China	No company website found.	21,600	2	Can't confirm address.
Shandong Rongcheng Municipal Supply Ltd.	No.1666, Donghuan Road, Juancheng County, Shandong Province, China 274600	http://en.yangchengshengwu.com/comcontent_contact.html	19,440	1	The import address is for a Shandong Yangcheng Biotech Co., Ltd.
Yueqing Vancol Import and Export Co., Ltd.	No.7,Yongxing Yi Road, Chengdong Industrial Zone, Yueqing, Wenzhou,China 325600	http://www.vancol.cn/contactus.html	18,680	1	The address on the import records is the same as Vancol Electric co. Ltd. in China.
New Life Chemical and Equipment	No company address found.	No company website found.	16,884	1	Import address listed is incomplete. There is a company in the US with ths same name.
Foodchem International Corporation	Building 9,2277 Zuchongzhi Road,Shanghai,201203, China	https://www.foodchem.cn/pages/Contact/	12,510	1	Address Confirmed.
Nanjing Nutrabuilding Bio Tech Co. Ltd.	Room 1504 Suning Huigu Building 1 No. 268 Jiqingmen Street, Nanjing 210000 CN	No company website found.	12,375	1	Can't confirm address.
China Sinopharm International Corporation (Shanghai) C., Ltd.	293 Jiangning Road, Jing'an District, Shanghai, 200041	http://www.sinopharmintlsh.com/contact/	11,100	1	Address Confirmed.
Eumex Line Shenzhen Limited	Room J 26F., International Trade & Commercial Building, 3005 Nanhu Road, Shenzhen, China 518001	No company website found.	11,060	1	Address Confirmed.
Hebei Changhao Metal Wire Product Ltd.		No company website found.	11,060	1	Import address listed is incomplete.
Northeast Pharma Import and Export	19th Floor, Block B, Chamber of Commerce head quarter Mansion. No.51, The Youth Str., Shenhe Dist., Shenyang, China. 110014	No company website found.	10,368	1	The name of the company is possibly Northeast Healthcare Co., Ltd.
Qingdao Samin Chemical Co.,LTD.	B-3A20, Heda Plaza 179 Tailiu Road, Qingdao, China	http://www.saminchemical.com/	10,066	1	Address Confirmed.

BETA ALANINE CHINESE MANUFACTURERS / EXPORTERS LIST
02/01/19 - 01/31/20

COMPANY	HQ Address	Website	TOTAL KILOGRAMS EXPORTED TO THE U.S. (1)	TOTAL # OF SHIPMENTS EXPORTED TO THE U.S. (1)	NOTES
CTS Logistics Corporation	Nanjing Anjing Branch Room 4202, NO.288 Zhongshan East Nanjing, China	No company website found.	8,800	1	Cant' confirm address. The company may be CTS International Logistics Corporation Limited.
Changzhou Meiang International Trade	2620,15 Huangshan Road, Changzhou, Jiangsu, China	No company website found.	8,460	1	Can't confirm address.
Jinan Asia Pharmaceutical Co., Ltd.	Xinshi Town, Jiyang County Jinan, Shandong 250014 China (Import record address) Zhonghong Plaza, Jiefang Est Road, Jinan, China (Website Address)	http://hl-asia.net/AboutMe.aspx?t=4&lan=en	7,800	1	Address Confirmed.
Sun Chemical Trading Co. Ltd.	Room A, 7/F, China Overseas Building, 139 Hennessy Road Wanchai Honk Kong, China	No company website found.	4,810	1	Can't confirm address.
SYNMR Biotechnology (Shanghai) Limited	Union Energetic International Tower, New Jingqiao Rd, Pudong., Shanghai	http://www.synmr.com/about.html	4,492	1	Address Confirmed.
TOTAL			2,313,210	124	

Note (1) - Data was retrieved from PIERS TI import database.