FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 7, 2019

Zhang Xiao Dong
(b) (6)

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2019-N-3474

Dear Zhang Xiao Dong:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order under section 306(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 335a(b)(1)(C)) that would debar you for a period of five years from importing articles of food (including dietary supplements) or offering such articles for import into the United States. FDA bases this proposal on a finding that you were convicted, as defined in section 306(l)(1)(B) of the Act (21 U.S.C. § 335a(l)(1)(B)), of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. This letter also offers you an opportunity to request a hearing on this proposal and provides you with the relevant information should you wish to acquiesce to this proposed debarment.

Conduct Related to Conviction

On December 20, 2018, you were convicted as defined in section 306(l)(1)(A) of the Act (21 U.S.C. § 335a(l)(1)(A)), in the United States District Court for the Northern District of Texas Dallas Division, when the court entered judgment against you for the offense of Mail Fraud in violation of 18 U.S.C. § 1343. The underlying facts supporting this conviction are as follows:

As contained in the Factual Resume in your case, filed on March 12, 2018, you, along with other employees of your employer Genabolix USA, Inc. and Shanghai Yongyi Biotechnology Co., Ltd. (Genabolix), did in or around February 2017, agreed to sell synthetic stimulant ingredients, including 1,4 Dimethylamylamine (1,4-DMAA), to a purported dietary supplement manufacturer. That manufacturer told you that the ingredients supplied by you would not be accurately listed on the labels of the finished dietary supplements produced with those ingredients. As you knew, the synthetic stimulant ingredients would be omitted from the ingredient label of the dietary supplements so that American retailers would sell the product. You then sent unlabeled shipments of these ingredients to a third party in the United States. Subsequently, on June 8, 2017, you (along with others) caused 50kg of 1,3 Dimethylamylamine (1,3-DMAA) to be shipped via commercial carrier in interstate commerce in the United States.

FDA's Finding

Section 306(b)(1)(C) of the Act (21 U.S.C. § 335a(b)(1)(C)) permits FDA to debar a person from importing an article of food or offering such an article for import into the United States. An individual who has been convicted of a felony for conduct relating to the importation into the United States of any food may be subject to debarment, as set forth in section 306(b)(3)(A) of the Act (21 U.S.C. § 335a(b)(3)(A)). FDA finds that the felony count for which you were convicted was for conduct relating to the importation of an article of food into the United States because you conspired to falsely label synthetic stimulant ingredients such as DMAA, among others, with knowledge that the ingredients would be used to manufacture dietary supplements. The maximum period of debarment for each felony under section 306(c)(2)(A)(iii) of the Act (21 U.S.C. § 335a(c)(2)(A)(iii)) is five years. Section 306(c)(3) of the Act (21 U.S.C. § 335a(c)(3)) provides six factors for consideration in determining the appropriateness of and period of permissive debarment for an individual. Those factors relevant to the debarment of an individual for a felony conviction for conduct relating to the importation

into the United States of any food include, but are not limited to:

1. the nature and seriousness of any offense involved,

2. the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

3. the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including . . . full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing) . . . and any other actions taken to substantially limit potential or actual adverse effects on the public health,

4. whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future, and

5. prior convictions under the Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

FDA has determined that three of these factors are applicable for consideration:

1. Nature and seriousness of any offense involved.

As described in detail above, you were convicted of the following offense: Mail Fraud in violation of 18 U.S.C. § 1343. The Agency finds that your conduct seriously undermined FDA's regulation of the introduction of food (which includes dietary supplements) that has been imported into the United States into interstate commerce and the labeling of such food and dietary supplements. The false labeling could mislead the American consumer, who relies on the ingredient list of dietary supplements, and could pose a serious health risk to the public. Additionally, the ingredients which you imported into interstate commerce pose an acute safety risk, especially when they are not declared on the label due to their nature as stimulants. Accordingly, FDA concludes that the nature and seriousness of the offense involved supports the maximum possible period of debarment.

2. Nature and extent of voluntary steps to mitigate the impact on the public of any offense involved.

In determining the period of a debarment, FDA is also to consider the nature and extent of voluntary steps taken to mitigate the impact on the public of any offense involved, including, among other things, full cooperation with any investigation (including the extent of disclosure to appropriate authorities of all wrongdoing) and any other actions taken to substantially limit potential or actual adverse effects on the public health. The FDA is unaware of any steps you took to mitigate the impact on the public of your actions, which undermined the integrity FDA's regulation of the importation of food, into the United States and the introduction of such food into interstate commerce.

FDA considers your failure to take any steps to mitigate the potential impact on the public supports a negative factor.

3. Prior convictions under the Act or involving matters within the jurisdiction of FDA.

FDA is unaware of any prior criminal convictions involving matters within the jurisdiction of FDA. The Agency will consider this as a favorable factor.

<u>Proposed Action and Notice of Opportunity for Hearing</u>

Weighing all factors, FDA concludes that the facts supporting the unfavorable factors outweigh those supporting the

favorable factor, and therefore warrant the imposition of a maximum five-year period of debarment. FDA therefore proposes to issue an order under section 306(b)(1)(C) of the Act (21 U.S.C. § 335a(b)(1)(C)) that would debar you from importing articles of food or offering such articles for import into the United States for a period of five years. You were convicted of mail fraud related to your unlawful importation of synthetic stimulant ingredients which you then caused to be shipped in interstate commerce and ultimately used in dietary supplements that did not list the synthetic stimulants as an ingredient. As such, the FDA finds that the felony conviction was for conduct related to the importation into the United States of any food. FDA proposes that the felony offense be accorded a debarment period of five years.

In accordance with section 306 of the Act (21 U.S.C. § 335a) and 21 CFR part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred.

If you decide to seek a hearing, you must file the following: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing; and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. § 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing concerning your debarment and a waiver of any contentions concerning this action. If you do not request a hearing in the manner prescribed by the regulations, FDA will not hold a hearing and will issue a final debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny your request for a hearing and enter a final order of debarment.

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction supports your debarment under section 306(b)(1)(C) of the Act (21 U.S.C. § 335a(b)(1)(C)) as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2019-N-3474 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You must file four copies of all submissions pursuant to this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 C.F.R. § 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

You also may notify FDA that you acquiesce to this proposed debarment. If you decide to acquiesce, your debarment shall commence upon such notification to FDA in accordance with section 306(c)(2)(B) of the Act (21 U.S.C. § 335a(c)(2)(B)).

This notice is issued under section 306 of the Act (21 U.S.C. § 335a) and under authority delegated to the Director, Division of Enforcement, Office of Regulatory Affairs pursuant to FDA Staff Manual Guide 1410.35.
If you believe you are not the Zhang Xiao Dong to whom this letter is addressed, please contact us at (240) 402-8743.

Sincerely,

/s/
Scott J. MacIntire
Director
Division of Enforcement
Office of Enforcement and Import Operations
Office of Regulatory Affairs
U. S. Food and Drug Administration

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