SANTEC Chemicals Corp.

96 Gazza Blvd.,
Farmingdale, NY11735
U.S.A

Phone 718-461 2338
Fax 718-939 4995
E-Mail: Sales@SantecChemCorp.com

To: US Public Health Service, Division of Compliance & Enforcement
Office of Regulatory Affairs, US FDA

Date: 5/12/2024

Re: Docket No.FDA-2024-N-0604

Attn.Ms.Catherine M. Beer, Captain

Please kindly refer to your letter of Mar.18,2024, Notice of Opportunity for Hearing about the subject case, and our letter of Mar.30, 2024 requesting a hearing be arranged submitted online.

In the letter, the two of three factors applicable for considerations in this case are considered 'negative', mentioned in your letter under titles as below:

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

With this letter, we'd like to provide FDA with more information on the offense that caused the sentence, which was entered based on the Presentence Investigation Report-2023.07.10 (**Information A**) and my Plea Agreement (**Information B**). Hope these information will also help you address the above two factors in your consideration.

For this offense, for which the investigation commenced in April 2020, our supplier in China shipped the product 'Dipyrone' as 'Sebacic acid' (**Information A, page 3 -- Offense Conduct, 4**), to avoid a unreasonable testing requirement in China, as explained to court in my Mitigation Letter (**Information C, page 1**); Upon receipt, I relabeled it back into its correct name and shipped it to our customers in its correct name in US, as reflected in Presentence Investigation Report-2023.07.10 (**Information A, page 4 --The Offense Conduct, 8)**.

As I had failed to locate any proper FDA approval information for this drug ingredient 'dipyrone' during the court process, I felt I might have been selling an illegal drug ingredient by mistake, thus had signed the above Plea Agreement, and got the sentence FDA currently concerned about.

Not long after the sentence, to my surprise, I googled and located 'List of Bulk Drug Substances for Compounding Office StockDrugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals; Request for Nominations', a notice by FDA issued on 11/20/2019 (**Information D**), and 'Dipyrone' was one of the eight bulk drug substances allowed for certain sales (**Information D**, **Page 5**), our sales were for such allowed uses, as the final customer was Wedgewood Pharmacy (**Information**

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E, Durbin's email 20190315 requesting quote for Wedgewood showing the end-user as Wedgewood Pharmacy; **Information F:** Q1 2019 RFP - Wedgewood inquiry list, 'Dipyrone' listed under item#15) who is the only major party working with FDA on the workable list of animal drug ingredients (**Information D, page 2**).

This list was issued per FDA Draft Guidance for industry #256 entitled “Compounding Animal Drugs from Bulk Drug Substances” (GFI #256). "The draft guidance describes circumstances under which FDA, based on our current understanding of the risks of animal drugs compounded from bulk drug substances, does not intend to take action against pharmacists in either State-licensed pharmacies or Federal facilities, or veterinarians, who compound animal drugs from bulk drug substances." (**Information C, page 4**)

Thus, to my understanding, if I have had the above information before the sentence of the above offense, I should have presented it to the court and the court should have treated the sales of the product differently.
Though the shipment of the product by the supplier in China using a different chemical name was still an issue (Please note we have since strictly prohibited, and would refuse, any shipments using a different product name from it is, from our oversea suppliers), but I or Santec Chemicals Corp shouldn't have been punished for their wrongdoing.

With the above information, wish FDA may find that our sales of dipyrone to Wedgewood Pharmacy via different distributors, during 2019/2020 at least, was an action that falls into a category that FDA did not intend to take action against, 'based on our current understanding of the risks of animal drugs compounded from bulk drug substances'. (**Information C, page 4**). Those sales were thus not supposed to create any negative 'impact on the public', as confirmed by the customers mentioned above in the Presentence Investigation Report-2023.07.10.

Hope the above new information may help address FDA's concerns and my business may be waived from the suggested debarment punishment, though it is too late for us to stop the sentence by the Department of Justice!

Your kind consideration appreciated!

Thanks & Best regards

Wilson Jiao, VP
Santec Chemicals Corp.

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Attachments:

Information A: the Probation Dept's Presentence Investigation Report-2023.07.10
Information B: Plea Agreement
Information C: Mitigation Letter
Information D: List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals; Request for Nominations'
Information E: Durbin's email 20190315 requesting quote for Wedgewood
Information F: Q1 2019 RFP - Wedgewood inquiry list