REGION 4
ATLANTA, GA 30303

SENT VIA ELECTRONIC MAIL

Manesh Dixit
Owner
USpharma Ltd
13900 NW 57th Ct
Miami Lakes, FL 33014
manesh@uspharmaltd.com

Re: Request for Information
USpharma Ltd

Dear Manesh Dixit:

On March 22, 2024, the U.S. Environmental Protection Agency began an investigation of the USpharma Ltd facility located at 13900 NW 57th Ct, Miami Lakes, Florida to determine compliance with the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA). The EPA is requesting information to determine compliance with Section 312 of EPCRA, 42 U.S.C. § 11022 and Section 313 of EPCRA, 42 U.S.C. § 11023, and the regulations promulgated at 40 C.F.R. Parts 370 and 372, respectively. The information request is enclosed with this letter (Enclosure 3).

Please respond electronically within 15 calendar days of the receipt of this correspondence to:

Chetan Gala
South Air Enforcement Section
Air Enforcement Branch
Enforcement and Compliance Assurance Division
U.S. Environmental Protection Agency, Region 4
61 Forsyth Street, S.W.
Atlanta, Georgia 30303
Gala.Chetan@epa.gov

Pursuant to the regulations found at 40 C.F.R. Part 2, Subpart B, including 40 C.F.R. § 2.301, you are entitled to assert a claim of business confidentiality for any information you provide to the EPA that involves trade secrets and which you regard as confidential business information (CBI). For such information, you may request that the EPA treat such information as confidential. Any such claim of confidentiality must conform to the requirements of 40 C.F.R. § 2.203(b). For detailed instructions for claiming confidentiality, please see Enclosure 1. Information you supply under a claim of confidentiality

will be treated in accordance with 40 C.F.R. Part 2, Subpart B, and will be disclosed by EPA only to the extent, and by means of the procedures, set forth in 40 C.F.R. Part 2, Subpart B. If no such claim accompanies the information when it is received by EPA, it may be made available to the public by EPA without further notice to you. Please note that any confidentiality claim does not obviate the need to send that portion of the response to the EPA.

This request is not subject to the Paperwork Reduction Act, 44 U.S.C. §§ 3501 – 3520, because it seeks information from specific individuals or entities as part of an investigation.

If you have any questions regarding this request, you should contact this office prior to the deadline specified above. Please direct questions to Chetan Gala of my staff at Gala.Chetan@epa.gov or (404) 562-9746.

Sincerely,

TODD GROENDYKE

Digitally signed by TODD GROENDYKE
Date: 2024.03.25 11:40:28 -04'00'

Todd Groendyke
Chief
South Air Enforcement Section

Enclosures

Cc:

nelson.gonzalez@uspharmaltd.com
emily.leal@uspharmaltd.com

ENCLOSURE 1

Confidential Business Information (CBI)
Assertion and Substantiation Requirements

A. Assertion Requirements

You may assert a business confidentiality claim covering part or all of the information, other than emissions data and information or data that is otherwise publicly available, as described in 40 C.F.R. § 2.203(b). If no business confidentiality claim accompanies the information when it is received by the EPA, the EPA may make the information available to the public without further notice. To make a confidentiality claim, submit the requested information and indicate that you are making a claim of confidentiality. Any information over which you make a claim of confidentiality should be marked by placing on or attaching to the information, at the time it is submitted to the EPA, a cover sheet, stamped or typed legend, or other suitable form of notice employing language such as "trade secret" or "proprietary" or "business confidential" and a date if any when the information should no longer be treated as confidential. **You must be specific by page, paragraph, and sentence when identifying the information subject to your claim.** Allegedly confidential portions of otherwise non-confidential documents should be clearly identified. Information covered by such a claim will be disclosed by the EPA only to the extent permitted and by means of the procedures set forth by 40 C.F.R. Part 2, Subpart B. The EPA will construe the failure to furnish a confidentiality claim with your response to the attached letter as a waiver of that claim, and the information may be made available to the public without further notice to you.

Please segregate personnel, medical and similar files from your responses and include that information on separate sheet(s) marked as "Personal Privacy Information" given that disclosure of such information to the general public may constitute an invasion of privacy.

B. Substantiation Requirements

All confidentiality claims are subject to EPA verification and must be made in accordance with 40 C.F.R. Part 2, Subpart B.[1] You bear the burden of substantiating your confidentiality claim and must satisfactorily show, among other things, that you have taken reasonable measures to protect the confidentiality of the information and that you intend to continue to do so and that the information is not, and has not been, reasonably obtainable by legitimate means without your consent. Conclusory allegations will be given little or no weight.

Before the EPA makes a final determination regarding your claim of confidentiality, pursuant to 40 C.F.R. Part 2, Subpart B, the EPA will send you a letter asking you to substantiate fully your CBI claim by answering several questions. Your comments in response to these questions will be used by the EPA to determine whether the information has been shown to meet the requirements so as to be entitled to confidential treatment. You must provide the EPA with a response within the number of days set

[1] 40 C.F.R. § 2.208(e) conflicts with the holding in *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019) (*Argus Leader*). In light of the *Argus Leader* decision, the Agency will not consider 40 C.F.R. § 2.208(e) in this determination. The Agency anticipates amending 40 C.F.R. § 2.208 so that it is consistent with the decision in *Argus Leader*.

forth in the EPA request letter. Failure to submit your comments within that time will be regarded as a waiver of your confidentiality claim or claims, and the EPA may release the information.

The EPA will ask you to specify which portions of the information you consider confidential. You must be specific by page, paragraph, and sentence when identifying the information subject to your claim. Please note that if a page, document, group or class of documents claimed by you to be confidential contains a significant amount of information which the EPA determines is not confidential, your confidentiality claim regarding that page, document, group or class of documents may be denied. For each item or class of information that you identify as being confidential, the EPA will ask you to answer the following questions, giving as much detail as possible, as conclusory allegations will be given little or no weight in the EPA's determination:

1. For what period of time do you request that the information be maintained as confidential, e.g., until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.

2. Information submitted to the EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question #1?

3. What measures have you taken to protect the information claimed as confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information be considered confidential?

4. Is the information contained in any publicly available material such as the Internet, publicly available databases, promotional publications, annual reports, or articles? If so, specify which.

5. Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?

6. Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.

7. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If you assert that the information is voluntarily submitted information, please explain whether the information is the kind that would customarily not be released to the public.

8. Whether you assert the information as voluntary or involuntary, please address why disclosure of the information would tend to lessen the availability to the EPA of similar information in the future.

9. If you believe any information to be (a) trade secret (s), please so state and explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be (a) trade secret (s).

10. Explain any other issue you deem relevant (including, if pertinent, reasons why you believe that the information you claim to be CBI is not emission data or effluent data).

Information designated confidential will be disclosed by EPA only to the extent allowed by, and by means of procedures set forth in, 40 C.F.R. Part 2, Subpart B. If you fail to claim the information as confidential, it may be made available to the public without further notice to you.

ENCLOSURE 2

Instructions

1. Please submit your response to this information request to the EPA electronically. You may submit your response using either of the following options: (A) As an attachment sent via email to Chetan Gala at gala.chetan@epa.gov; or (B) by requesting a link from the EPA for a secure file transfer site where you may upload your response. You may request a link by sending an email to Chetan Gala at gala.chetan@epa.gov.

2. Please do not submit compressed files (.zip) via email. If you wish to submit compressed files, please select option B.

3. Please do not send documents that you have claimed as confidential business information (CBI) to the EPA by email (option A). If you are submitting documents that you have claimed as CBI, please upload them to the EPA's secure file transfer site (option B).

ENCLOSURE 3

Request for Information

1. Provide all Standard Industrial Classification Codes and North American Industrial Classification System Codes under which this facility conducts business.

2. Provide the total number of:

    a. full time employees who worked at, or directly for, the facility during calendar years 2020, 2021 and 2022, including operational staff, administrative staff, contractors, dedicated sales staff, company drivers, and off-site direct corporate support; and

    b. hours of part-time employees who worked at, or directly for, the facility during calendar years 2020, 2021, and 2022, including operational staff, administrative staff, contractors, dedicated sales staff, company drivers, and off-site direct corporate support.

3. Provide an inventory list of all extremely hazardous substances (EHS) listed in 40 C.F.R. § 355, Appendices A and B, brought onsite and/or stored onsite between January 1, 2020, and December 31, 2023. For each extremely hazardous substance, indicate the maximum quantity in pounds stored on site at any one time for each calendar year 2020, 2021, 2022, and 2023.

4. Provide an inventory list of all hazardous chemicals (as defined by Section 329(5) of EPCRA, 42 U.S. Code § 11049(5), brought onsite and/or stored onsite between January 1, 2020, and December 31, 2023. For each hazardous chemical, indicate the maximum quantity in pounds stored on site at any one time, for each calendar year 2020, 2021, 2022, and 2023.

5. Provide an inventory list of all toxic chemicals listed in 40 C.F.R. § 372.65 that you manufactured, processed, or otherwise used between January 1, 2020 and December 31, 2022. For each toxic chemical, indicate the total quantity in pounds that was manufactured, processed, or otherwise used, for each calendar year 2020, 2021, and 2022.

6. Provide an inventory list of all bulk chemicals manufactured, processed, or otherwise used during calendar years 2020, 2021, and 2022, not already provided in response to question 4-6. For each bulk chemical, indicate the total quantity in pounds that each chemical was manufactured, processed, or otherwise used, for each calendar year 2020, 2021, and 2022.

7. Provide a copy of any Safety Data Sheet for bulk hazardous chemicals present on site at any one time in quantities at or above 10,000 pounds and for any EHS present on site at any one time in quantities at or above its threshold planning quantity (TPQ) or 500 lbs during calendar years 2020, 2021, 2022 and 2023.

8. Provide copies of the Emergency and Hazardous Chemical Inventory (Tier I or Tier II Inventory) that were submitted for this facility for calendar years 2020, 2021, 2022, and 2023. Also

provide evidence that you submitted each inventory to the State Emergency Response Commission, the Local Emergency Planning Committee, and the local fire department.

9. Provide copies of the Toxic Release Inventory Forms (Form R/Form A) that were submitted to the EPA for each chemical for calendar years 2020, 2021, and 2022.

10. For all EPCRA section 313 chemicals manufactured, processed, or otherwise used in quantities greater than the reporting threshold listed in 40 C.F.R. § 372.25 or 372.28 between January 1, 2020 and December 31, 2022, please provide the total annual quantity of the EPCRA section 313 chemical in wastes sent to any off-site facility for the purposes of disposal, treatment, combustion for energy recovery, or recycling.

11. For all EPCRA section 313 chemicals manufactured, processed, or otherwise used in quantities greater than the reporting threshold listed in 40 C.F.R. § 372.25 or 372.28 between January 1, 2020 and December 31, 2022, provide all analytical data, sampling data, and estimates used to determine the amount of the chemical released to any water media.