

**BEFORE THE HON'BLE NATIONAL GREEN TRIBUNAL SOUTHERN ZONE
BENCH AT CHENNAI
O.A No. 126 OF 2021**

IN THE MATTER OF:

M/S SRI MAHALAKSHMI HATCHERIES

Represented by its Proprietor
Mr. D. Sagar Reddy
S/o D. Venkata Ramana Reddy
Office at Doruvukatta Village, Kota Mandal
Sidavaram Post, Nellore- 524 411
Ph +91 8978374567
Email: sagar.duvvuru@gmail.com

APPLICANT

Versus

1. UNION OF INDIA

Through the Secretary
Ministry of Environment and Forests & Climate Change
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New Delhi 0110003.
Email: Secy-moef@nic.in

2. STATE OF ANDHRA PRADESH

Represented by its Chief Secretary
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Andhra Pradesh.
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Email: cs@ap.gov.in

3. THE DISTRICT COLLECTOR

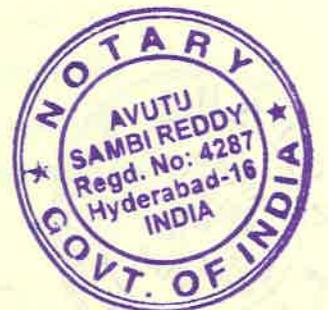
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**4. ANDHRA PRADESH COASTAL ZONE
MANAGEMENT AUTHORITY**

Represented by its Member Secretary
D.No. 33-26-14 D/2, Near Sunrise Hospital,
Pushpa Hotel Centre,
Chalamvari Street, Kasturibaipet,
Vijayawada 520010.
Ph 0866 2463200
Email: membersecy@appcb.gov.in

**5. ANDHRA PRADESH POLLUTION CONTROL
BOARD**

Represented by its Member Secretary,
D.No. 33-26-14 D/2, Near Sunrise Hospital,
Pushpa Hotel Centre,
Chalamvari Street, Kasturibaipet,
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Ph 0866 2463200.
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6. COASTAL AQUA CULTURE AUTHORITY

Represented by its Member Secretary
5th Floor, Integrated Office Complex for Animal
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Nandanam,
Chennai 600 035.
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7. M/S DIVIS LABORATORIES LIMITED

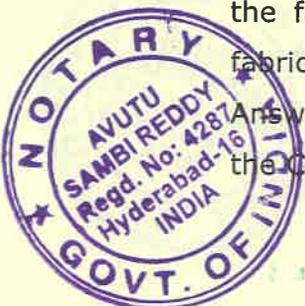
Represented by its Managing Director
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RESPONDENTS

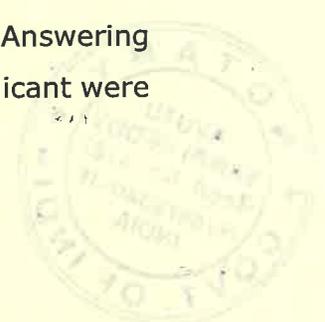
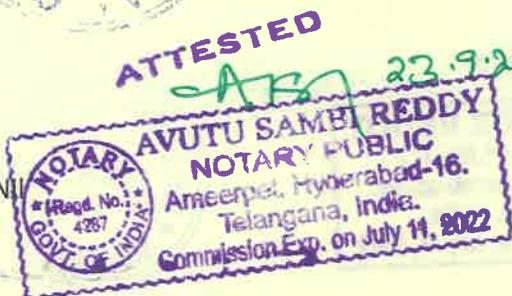
REPLY OF RESPONDENT NO. 7 TO COUNTER FILED BY RESPONDENT NO 6

I, K. Subba Rao, aged about 57 years, representing the 7th Respondent, having office at 1-72/23(P)/DIVIS/303, Divi Towers Cyber Hills, Gachibowli Hyderabad, Telangana, 500032 India, do hereby solemnly affirm and sincerely state as follows:

1. I am the General Manager (erstwhile Deputy General Manager) of the 7th Respondent herein and as such well acquainted with the facts of the case and competent to swear the present affidavit.
2. The contents of the Counter affidavit filed by the 6th Respondent are specifically denied except those which are specifically and expressly admitted hereto. Absence of any specific denial shall not be deemed to be an admission by Respondent No. 7 ("**Answering Respondent**"). The contents of the Counter filed by the Answering Respondent are a part and parcel of the present Reply and are not repeated herein for the sake of brevity. At the outset, the contentions raised by the 6th Respondent in the Counter, are generic, bereft of any merit and are legally untenable for reasons set for below.
3. The 6th Respondent has conveniently advanced only general submissions by quoting and referring to generic reports and statements and has failed to address the specific contentions against the 7th Respondent. Even though the 6th Respondent has made reference to a number of research articles and reports, it has failed to provide any explanation as the relevance of such reports, in light of the facts of the Application. The 6th Respondent has merely made bald and fabricated allegations without any iota of evidence on how the activities of the Answering Respondent will adversely affect the environment. It is submitted that the Counter filed is vague and is based on theories and assumptions.



4. It is highlighted that the core operational activities of the Answering Respondent do not hamper or cause any adverse effect to the aqua culture or its revenue. It is prima facie stated that the Answering Respondent shall function in compliance with all prescribed and applicable statutory norms and standards as prescribed by the Government pertaining but not limited to waste management handling and discharge of treated effluents.
5. Further, it is pertinent to note that the Marine outfall point has been consciously chosen based on the Marine EIA Studies carried out by Indomer Hydraulics (P) Limited, Chennai which is an empanelled accredited body of the Ministry of Environment, Forest & Climate Change (hereinafter referred to as MoEF). As per the recommendations of the aforementioned study, the treated effluents can be discharged into the sea at a distance of 1000 m/1km and depth of 8 m from the land fall point. The effluents will be treated in a diversified manner to ensure that they adhere to the standards prescribed by the 5th Respondent and are not directly discharged. Adequate mechanisms are put in place to monitor air pollution as well.
6. Pertaining to the concerns of discharge of treated effluents in the sea, it is submitted that the treated effluents would be stored in guard ponds which are duly facilitated with a lock and seal system in accordance with the norms prescribed by the 5th Respondent. The whole activity pertaining to discharge of the treated effluents would be done only in the presence of the officials of 5th Respondent, after receiving the necessary conformation based on treatments and standards prescribed by them. The proposed scheme of disposal of the other residue products like incineration ash, process salt and residue, used oil, spent acids, catalysts etc is further indicative of the fact that the Answering Respondent has only undertaken environmentally viable measures by sending such wastes to Treatment Storage and Disposal facilities (TSDF) or by sending them to duly authorised re-processors/ recyclers or agencies.
7. Additionally, it is pertinent to note that after submission of representation from the proprietor of the Applicant namely Mr. D. Sagar Reddy and the preliminary Joint inspection report, the respective parties along with the members of the joint inspection committee were asked to make representations before the Consent for Establishment (CFE) Committee to discuss the said issue on 22.10.2020 through video conference. In accordance with the same, all respective parties appeared and were duly given an equal opportunity to represent their claims. After detailed deliberations of all the issues and claims and careful scrutiny, the CFE Committee granted CFE (NOC) for marine outfall facility under section 25 of the Water (Prevention & Control Pollution Act) 1974 and Section 21 of the Air (Prevention & Control of Pollution) Act, 1981 and the rules made thereunder to the Answering Respondent. It is pertinent to note that all objections raised by the Applicant were



examined in detail and only subsequent to which the CFE (NOC) for Marine outfall in favour of the Answering Respondent was issued based on scientific reasons.

8. Furthermore, it is hereby submitted that the State Level Environment Impact Assessment Authority (SEIAA) in its meeting held on 20.06.2021, examined the proposal submitted by the Answering Respondent along with the recommendations made by State Expert Appraisal Committee (SEAC) and has decided to accept the recommendations of SEAC for strict compliance by the Answering Respondent and accorded Environment Clearance to the Project vide letter dated 28.06.2021 bearing Order No. SEIAA/ AP/ VSP/ IND/ 07/ 2020/ 1971/ 157.09/ 153.11.318 under the provisions of EIA Notification 2006 subject to the implementation of the specific and general conditions annexed with the Environment Clearance order pertaining to waste handling, air and noise environment, discharge of effluents, water environment, Wastewater generation, Solid Wastes handling etc. Therefore, the averments that any such industrial discharge into the sea will have adverse effects on the production and agriculture is misconceived and hence denied.

Without prejudice to the above contentions, the para wise response of the Answering Respondent to the contentions of the 6th Respondent as under:

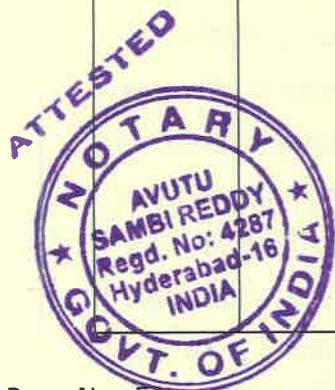
DETAILED OBJECTIONS: PARA WISE REPLY

Para	Reply
1-12	<p>With respect to paragraphs 1-12, they pertain to generic statements made on basis on facts; reports; establishment, powers and functions of the 6th Respondent; objective, overview and scope of the Coastal Aquaculture Authority Act, 2005, general observations on Hatcheries, pH, salinity, certification etc. and do not merit any response from the Answering Respondent. It is submitted that functioning of the Answering Respondent is closely monitored by the other Respondents and routine inspections are conducted from time to time to ensure that the Answering Respondent is in compliance with all applicable standards and norms, which is explained in detail in the routine inspection report submitted by the 5th Respondent from time to time. Due prior examination and analysis of treated effluents will be undertaken in the 5th Respondents zonal laboratory before discharging at the Marine outfall point. Thus, it is submitted that the core operational activities of the Answering Respondent would not hamper or cause any adverse effect to the aqua culture or its revenue.</p>



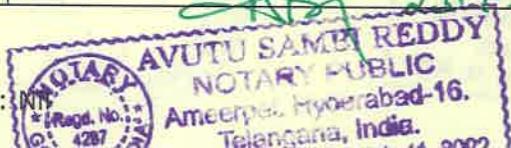
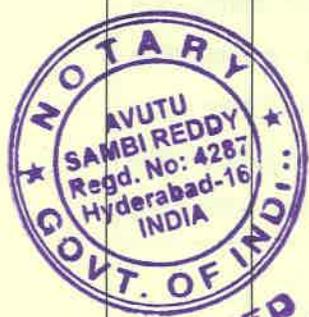
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- (i) With respect to paragraph 13, the contents are generic and prima facie, do not warrant a reply from the Answering Respondent. However, in light of the bigger picture, it is stated that, the picture as painted by the 6th Respondent represents a potential situation when the standards prescribed under law are not adhered to, which is not the situation in the present case as the functioning of Answering Respondent is wholly in adherence to law. Therefore, the averments advanced by the 6th Respondent that any such industrial discharge into the sea will have an adverse effect on the production and farming undertaken in the Hatcheries, is misconceived and hence denied.
- (ii) It is reiterated at the cost of repetition that the Answering Respondent strictly complies with all necessary standards and procedures as prescribed under the appropriate legislative frameworks. Re-emphasis is placed on the fact that hazardous waste i.e., solid waste will not be disposed into the sea at any instance or cost. Such waste shall be duly sent to TDSF/co-processors/ recyclers/ authorised vendors. There is no uncontrolled discharge as alleged by the 6th Respondent made by the Answering Respondent and the 6th Respondent is put to strict proof of the same.
- (iii) The information and documents available on record are indicative of the comprehensive and highly standardised process adopted by the Answering Respondent to prevent pollution of any kind by stringently adhering to abide by every requirement under law. The Answering Respondent has duly undertaken to strictly function in compliance with rules and regulations issued under all applicable laws, including laws relating to the protection of the Environment such as Environment (Protection) Act, 1986, Water (Prevention and Control of Pollution) Act, 1974 and Air (Prevention and Control of Pollution) Act, 1981. It is further highlighted that the Answering Respondent has undertaken to adhere to and follow a standard treatment process which would be environmentally viable and safe and would not bring any harm to the surrounding environment which includes the sea water or any species therein.
- (iv) Additionally, the pharmaceutical concentration in the effluents from the proposed unit shall be closely and frequently analysed and monitored in order to ensure that the pharmaceutical concentration in effluents is in line with the applicable standards prior to any discharge. It is submitted that the Answering Respondent shall be allowed to discharge effluent only if the ratio of PEC (Predicted Environmental Concentration) & PNEC (Predicted No Effect Concentration) is less than 1 ppm and those effluents



having >1 ppm will be directly subjected to Forced Evaporation Systems. It is pertinent to note that, only after obtaining the mandatory approval from the concerned regulatory body, the Answering Respondent shall release the effluents in sea. Further, only if the API concentration is less than 1 ppm the effluents will be allowed for discharge as mentioned in the scope of release.

- (v) A pre-analysis of treated effluents shall be carried at both inhouse and externally by PCB Zonal Laboratory for various parameter prior to discharge. The effluents shall be treated in the sophisticated facilities until they attain the Dissolved Oxygen ("DO") concentration of 4ppm. As per the notification issued by Ministry of Environment, Forest & Climate Change & CC Govt. of India, the Answering Respondent is meticulously in line with all the stipulations and the treated effluents would be in the Safe Exposure Levels.
- (vi) It is pertinent to note that the Marine outfall point has been consciously chosen and specifically designated by considering various parameters like Dispersion modelling study, Rate of dilution, Marine impact assessment, all based on the Marine EIA Studies carried out by Indomer Hydraulics (P) Limited, Chennai which is an empanelled accredited body of the Ministry of Environment, Forest & Climate Change. As per the recommendations of the aforementioned study, the treated effluents can be discharged into the sea at a distance of 1000 m and depth of 8 m from the land fall point, where the treated affluents attain the maximum dilution. Adequate mechanisms are put in place to monitor air pollution as well.
- (vii) Further, the effluents will be treated in a diversified manner to ensure that they adhere to the standards prescribed by the 5th Respondent and are not directly discharged. In this regard, the 5th Respondent has formulated SOPs for monitoring marine outfall systems in the State. As per the SOPs, the industries which are permitted with marine outfall system, shall install online continuous effluent monitoring system to verify the status of the treated effluents being discharged into sea, which in turn is further linked with the Central Pollution Control Board (CPCB)/ 5th Respondent's website. It is submitted that, the treated effluents shall be stored in guard ponds, whose outlet pumping system is guarded under a lock & key facility. The treated effluents in the guard ponds shall be analysed by the 5th Respondent officials for its compliance with the norms of the board, and only after duly ensuring that the treated effluents are in compliance with the marine discharge standards prescribed by the Board, the



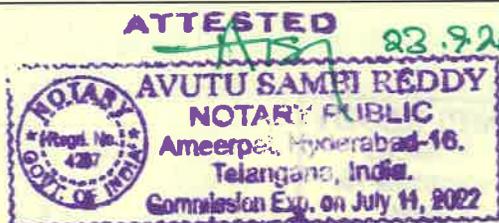
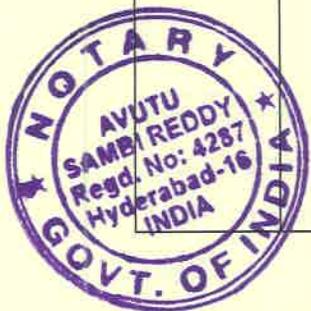
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discharge into the sea is carried out in the presence of 5th Respondent's officials. Online cameras focusing the guard ponds are installed and are connected to the 5th Respondent's servers for 24x7 surveillance. The 7th Respondent shall also conduct the Bio - Assay tests for analyzing treated effluent discharges from marine outfalls as per the MoEF&CC and CPCB guidelines, analysis reports shall be sent to APPCB every six months. The test species being used is Danio rerio (Zebra fish) which is very sensitive and broadly used for acute toxicity tests.

(viii) Furthermore, the Answering Respondent has duly obtained all the necessary clearances from the appropriate authorities. The committee of State Expert Appraisal Committee (SEAC) and the State Level Environment Impact Assessment Authority (SEIAA) have granted Environmental Clearance to the Answering Respondent after examining the project proposal; MOEF&CC OMs, CRZ Clearance from the 4th Respondent viz Andhra Pradesh Coastal Zone Management Authority (APCZMA); Consent for Establishment (CFE) from the 5th Respondent for laying of marine outfall facility to discharge treated effluent.

(ix) It is noteworthy that, during the CFE meeting conveyed by the 5th Respondent for determining a marine outfall facility to discharge treated effluents, the committee recommended that a meeting should be convened with the President and Secretary of All India Shrimp Hatcheries Association, Members of the Joint Inspection Committee and representatives of the industry to discuss the issue and to take a decision. Accordingly, the concerned representatives of the All India Shrimp Hatcheries Association, Members of Joint Inspection Committee and representatives from the industry were invited to participate in the CFE Committee meeting held on 22.10.2020 through Video Conference.

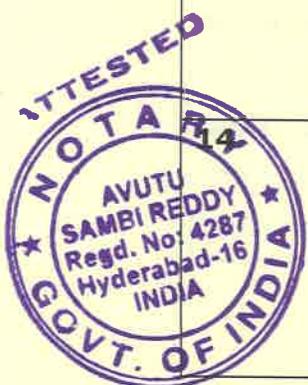
(x) The Joint Director-Fisheries, Deputy Director-Industries Department, and representatives of the All India Hatcheries Association, attended the meeting through video conference from Regional office: Nellore, APPCB. The views, apprehensions and suggestions of the joint committee members and the representatives of All India Shrimp Hatcheries Association were duly heard by the CFE committee. The members of the Association expressed their concern over presence of traces of antibiotics in the effluents discharged from pharmaceutical manufacturers in the area into the sea and that presence of the antibiotics in the shrimp may lead to rejection of the consignments of shrimp from the other countries. This aspect has been adequately responded



to and the Answering Respondent is not aware why the entire factual position has not been placed before this Hon'ble Tribunal.

- (xi) Firstly, as a part of the manufacturing, no production of antibiotic products are envisaged in the proposed manufacturing unit, thus there is no potential threat of any antibiotic APIs being present in discharge water. Further, based on the directions issued, the Answering Respondent shall install requisite flow meters to record the quantities of treated effluents discharge and shall regularly monitor coastal water through reputed institutions like NIO/NEERI for analysing the quality of water near the proposed outfall point. It is reiterated that, the Answering Respondent has undertaken to comply with all the standards stipulated by the 5th Respondent in the CFE/CFO in order to discharge the treated effluents.
- (xii) Secondly, with regard to the presence of antibiotics in the water, the 5th Respondent has clarified that, a series of meetings were conducted in the Secretariat regarding return/rejection of the aqua products by some of the European countries like U.K. etc. It was revealed that, the processing units processed the prawns collected from several farmers cultivating the aquaculture in different ponds, wherein it was observed that antibiotic residues were present in the processed aqua products. The Government of India and Fisheries Department, A.P. have taken steps to create awareness among the farmers to avoid usage of antibiotics. After detailed discussions and deliberation on specific issues, the committee recommended to issue NOC to the project proponent for establishment of marine outfall.
- (xiii) Thus, it is stated that, while the generic position as outlined by the 6th Respondent stated may be correct in circumstances where there are uncontrolled and unmonitored discharges, the issue does not arise for consideration in the present case, as the Answering Respondent shall function in compliance with all prescribed and applicable statutory norms and standards as prescribed by the Government pertaining but not limited to waste management handling and discharge of treated effluents. It is highlighted that the core operational activities of the Answering Respondent do not hamper or cause any adverse effect to the aqua culture or its revenue.

- (i) With respect to paragraph 14, the contents are non-specific and generic and thus, it is necessary to place on record the facts specific to the proposed unit of the Answering Respondent. The mortality of aquatic species is analysed using Bio - Assay Test. The test species being used for this project is Danio rerio (Zebra fish)



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which is very sensitive and is generally used as a test and marker for acute toxicity tests. The results of the study, show that the mortality of such species is almost zero. Pertinently, the document referred at Annexure – 3 by the 6th Respondent, is not related to Pharmaceutical Manufacturing Unit Treated water discharges and is not relevant for the present issue and the 6th Respondent is put to strict proof of the same. The reference placed on the article is wholly misconstrued and the Answering Respondent fails to comprehend why the 6th Respondent has referred to the same. Further, the article discusses that "Large centres of human population are often found in coastal areas and pharmaceutical releases via municipal effluent discharges are probable," due to consumption of antibiotic by Human and veterinary population.

(ii) The article annexed in Annexure – 3 further mentions about WWTPs of Sewage, which is wholly irrelevant to the 7th Respondent's Waste Water Treatment Plant. The opinion expressed is therefore inappropriate with two different aspects set out in a single sentence. The article further provides that "*Pond-based farms located in coastal areas are also a source of antibiotics entering coastal waters through leaks and discharge of wastewaters which can contain elevated concentrations of pharmaceuticals. Extremely high antibiotic concentrations of up to 2.5 mg l-1 were measured in water samples from shrimp ponds in Vietnamese mangroves [32].*" This is of extreme importance as it provides that pond based farms like the hatcheries, are a significant source of antibiotics accumulation.

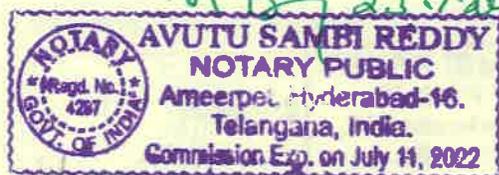
(iii) Pertinently, with regard to the issue highlighted in the article, in fact, proper treatment and disposal of hatchery discharge will reduce disease problems within the hatcheries. It appears that most hatcheries are run as open systems with regular intake of seawater, and they release effluents, which lead to water quality deterioration. Further, it is noteworthy that, only very few hatcheries employ wastewater treatment systems before discharging into the open environment. In the case of mortality due to a disease, dead animals are disinfected with chemicals and disposed of, either within the hatchery compound or outside the compound or into the sea closest to the hatchery operation. It is stated that controlling such activities would significantly contribute to the improvement the problems faced.

It is pertinent to note that the proposed unit is an API manufacturing industry and no fermentation process is proposed,



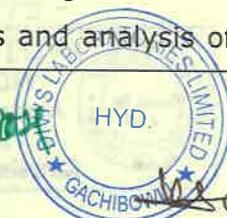
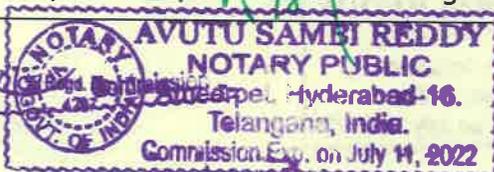
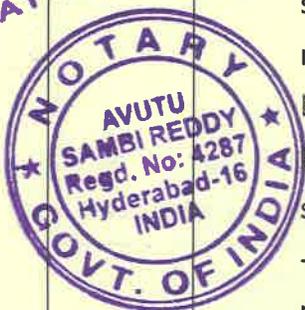
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	<p>therefore no antibiotic products shall be manufactured in the proposed unit and there shall be no presence of any antibiotic residue in the discharge water/treated effluent. Thus, as explained above, there can be multiple sources for such discharges and it is not acceptable to conveniently pass the liability on the Answering Respondent, who would strictly function in compliance with all the rules and regulations issued under all applicable laws, including laws relating to the protection of the Environment such as Environment (Protection) Act, 1986, Water (Prevention and Control of Pollution) Act, 1974 and Air (Prevention and Control of Pollution) Act, 1981.</p>
<p>15</p>	<p>(i) With respect to paragraph 15, the statements made are general and non-specific to the Answering Respondent and do not merit any response. However, without prejudice, it is submitted that the toxicity study of the treated effluent from effluent treatment plant is indispensable and shall be duly carried by the Answering Respondent in accordance with the MOEFCC/CPCB protocols. Further, it is submitted that, fishes are the primary bio indicators as they are very sensitive towards pollution and the overall observations of analyzed treated effluents show 100% Survival even after 96 hrs of discharge. This is conclusive of the fact that the effect of the Answering Respondent's treated effluents discharge on aquatic life is almost zero and the position set out conveniently by the 6th Respondent is wholly general and inapplicable to the preset set of facts.</p> <p>(ii) Further, the article relied by the 6th Respondent discusses the presence of pharmaceuticals in drinking water due to discharge of untreated and partially treated effluents of pharma industries into drinking water sources, but however fails to advance any evidence on presence of pharmaceuticals in drinking water due to marine discharge of treated wastewater. It is relevant to note that the proposed unit would be discharging the treated effluent after meeting the requisite discharge standards as stipulated by the 1st & the 5th Respondent. It is reiterated that; the treated effluents shall be stored in Guard ponds with lock and seal system as per norms laid by the 5th Respondent and the treated effluents shall be monitored and discharged only in the presence of the 5th Respondent officials after meeting the prescribed discharge standards. The Answering Respondent shall also conduct the Bio - Assay test for treated effluent discharges from marine outfall point as per the MoEF&CC guidelines and analysis of the reports</p>

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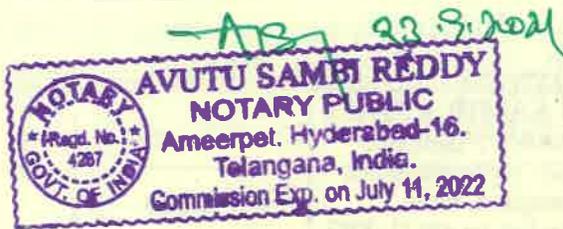
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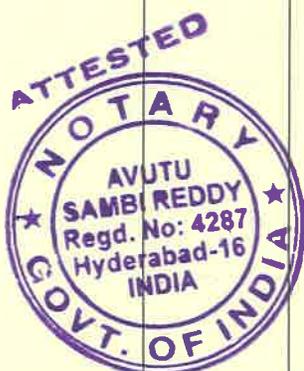
	shall be sent to the 5 th Respondent every six months. Further, the Answering Respondent has also undertaken to install Continuous Monitoring system to observe the impact on marine life/flora/fauna due to the discharge.
16	With respect to paragraph 16, the contentions are general and repetitive and the submissions made above pertaining to compliance of standards, rules and regulations are reiterated and not repeated herein for the sake of brevity. It is submitted that the Answering Respondent, as a vigilant organisation, has duly complied with all the Marine SOP guidelines issued by the 5 th Respondent to prevent unauthorised discharges. No discharges have been done without a prior consent from the 5 th Respondent up to date. The guard ponds are equipped with a comprehensive lock and seal facility where no drop of water can be discharged without the surveillance of the 5 th Respondent.
17	<p>(i) With respect to paragraph 17, the contents of this paragraph are also general and non-specific and do not pertain to the Answering Respondent. However, it is submitted that the Answering Respondent was established in the year 1995 and is currently operating two manufacturing units at Choutuppal and Visakhapatnam. As a part of environmental activities the Answering Respondent has conducted a proactive study along 5 kms buffer of all its units. The results are indicative of the fact that there is no impact on ground water due to the its activities or functioning. Further, CSIR-National Institute of Oceanography has been conducting post monitoring studies along the north coast of Andhra Pradesh. The results have concluded that there is, in fact, no impact caused due to the pharmaceutical industries within that area.</p> <p>(ii) Further, as iterated, a continuous vigilance mechanism will be put in place for around the clock monitoring of adherence to environment standards. A specific Environmental management plan has been incorporated and implemented effectively. As submitted above, it is important to note that no antibiotic products are proposed to be manufactured in the proposed manufacturing unit and thus, there shall not be any antibiotic APIs present in discharge water. Thus, the Answering Respondent does not promote the natural development of Antibiotic - resistance /Antimicrobial Resistance in the surrounding areas.</p>



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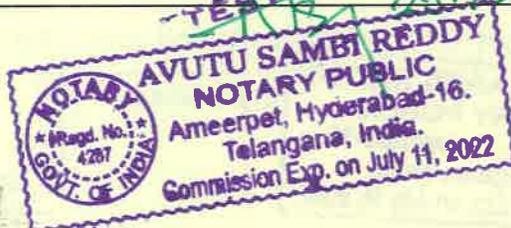
18	With respect to paragraph 18, the contents are general and non-specific and have been duly addressed by the Answering Respondent in the submissions above and in the counter affidavit and are not reiterated herein for the sake of brevity.
19	<p>(i) With respect to paragraph 19, the major averments are general and non-specific in nature. The one specific averment against the Answering Respondent is however baseless, misconceived and demonstrably incorrect and has been misinterpreted intentionally to show the Answering Respondent in poor light. The Answering Respondent takes a very serious objection to making of a partial statement by a responsible statutory authority to create a completely incorrect position. While setting out the position with respect to wastewater treatment, the 6th Respondent has unfortunately inserted a statement concerning a temporary action taken by the U.S. Food and Drug Administration (US FDA) concerning an 'import alert'. The said event which took place in 2016 - 2017 relates to the compliances against the current Good Manufacturing Practices (CGMP) against the US FDA code 21 CFR 210 and 211 which further relate to the quality compliance. The same has nothing to do with any alleged pollution and has no relevance in the present application in no manner whatsoever.</p> <p>(ii) In fact, it is pertinent to note that the Answering Respondent is one of the pioneers in obtaining FDA approval and has maintained an unblemished record. The Answering Respondent had proactively approached US FDA and duly provided detailed clarifications against the observations raised by US FDA within a short period of time. Based on the proactive approach of the Answering Respondent in providing clarifications, the US FDA was convinced to quickly schedule an inspection in 2017 which resulted in a "Satisfactory" rating followed by several other regulatory bodies. Further, the Answering Respondent has also demonstrated through its compliances by consistently getting quick and time bound approvals from the appropriate authorities.</p> <p>(iii) The specific incident, which is irrelevant to this present situation, is mischievously placed by the 6th Respondent and is a well-publicised event which the Answering Respondent had itself notified in compliance with its policy of full disclosure as also stock exchange listing requirements. The said event relates to the US FDA which had issued an import alert on March 20, 2017 on products manufactured at the Answering Respondent's Unit-II at Visakhapatnam for not meeting its current Good Manufacturing Practices (CGMP) related to the quality of the products</p>



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manufactured. This alert was a procedural event in the compliance process which was issued is one leading to detention without physical examination of drugs from firms which had not met Drug Good Manufacturing practises and is typically issued when an FDA inspection shows that a firm may not be operating in conformity with prescribed current Good Manufacturing Practises prescribed by the US FDA and not for any environmental breaches, as sought to be projected by the 6th Respondent. A copy of the warning letter dated 13th April 2017, produced herewith, would show the same. Upon such an alert being issued, compliance and adherence has to be established with specific inspections in that regard.

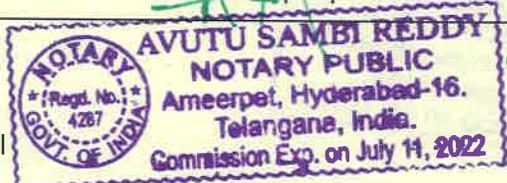
- (iv) In the Answering Respondent's case, the facility came under the import alert after the US drug regulator had not been satisfied with the remedial actions taken in connection with the Form 483 observations issued by the visiting inspection team during its audit from November 29-December 6 of 2016. Immediately, thereafter necessary steps were taken and the Import alert was lifted. This would be clear from the USFDA's communication dated 7th November 2017 and the Answering Respondent's communication dated 15th November 2017, to NSE, India, both of which are produced herewith. Significantly, the US drug regulator had exempted most of the products from its action citing their importance for an adequate supply of drugs made from these active ingredients in the US market.
- (v) After being satisfied with the compliance, within a short period, the alert was lifted. Unlike in other similar instances where the US FDA had taken punitive actions against Indian pharma companies, this Respondent was able to quickly ensure compliance. The Answering Respondent, is continuing to comply with the standards of US FDA, as would be evident from the communications received from them, in the subsequent years. Therefore, it is unfortunate that the Respondent should state that this event is a completely misleading manner without setting out the time of such event, what it concerned itself with and the fact that the US FDA itself was satisfied and lifted the alert. Further an impression is sought to be created that this is somehow related to pollution, when the US FDA action was solely concerned with CGMP compliances in adherence with certain specific directives, which were also quickly demonstrated. The subsequent
- (vi) The Answering Respondent is placing these full facts, in good faith to show the complete irrelevance of the said event and it is not known why a responsible statutory authority should place facts in such a manner before a judicial Tribunal.



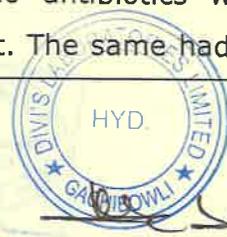
- (vii) In so far as the other aspects are concerned, Activated sludge (AS) was developed around 1912-1914. Usually, the effluent treatment plants were designed based on the effluent loads/characteristics i.e., COD, BOD, TDS etc., In the activated sludge process the microorganisms are utilized to biodegrade the organic materials present in the effluent. Further, the effluent will undergo various Unit Operations like Sedimentation, Clarification, Removal of Waste Activated Sludge to eliminate the suspended and dissolved organic content in the effluent.
- (viii) Further, waste water will be segregated based on the contents and characteristics of the streams. High concentrated effluents will be treated in Forced evaporation systems. There are many evidences that shows the activated sludge process will be effective for the treatment of pharmaceutical effluent. Hence, no organic matter will escape in to the water course.
- (ix) Further, the Answering Respondent has carried out the Marine EIA Studies by Indomer Hydraulics (P) Limited, Chennai which is an empanelled accredited body of the MOEF&CC along with Indian Remote Sensing (IRS), Anna University, Chennai as an authorised agency of Ministry of Environment, Forests and Climate Change for demarcation of CRZ area including HTL, LTL duly superimposing the activities on the map of approved CZMP to examine the location of the projects. As per the recommendations of the aforementioned study, the treated effluents can be discharged into the sea at a distance of 1000 m and depth of 8 m from the land fall point.
- (x) Further the output of MIKE 21 modelling studies indicate that the effluent get diluted to the order of 50 times at a distance of 250 mtrs from the proposed outfall during fair weather. During South-West monsoon and North- East monsoon periods due to combined action of wind and turbulent waves, it's observed that the effluent gets diluted to the order of 50 times within a distance of 50 mtrs from the proposed outfall. Study show that the impact due to the discharge of treated industrial effluent from the industry on the marine environment would be insignificant.

With respect to paragraph 20, the averments made by the 6th Respondent are misleading, incorrect and misrepresent the true factual scenario and the 6th Respondent is put to strict proof of the same. It is submitted that the line of activity of the Answering Respondent is manufacturing Active Pharmaceutical Ingredients (API) and no fermentation process is proposed and thus, no antibiotics will be manufactured in the proposed manufacturing unit. The same had been

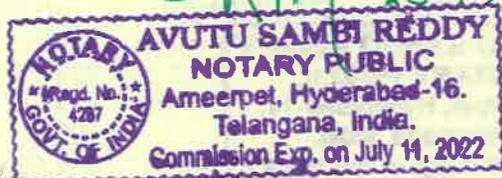
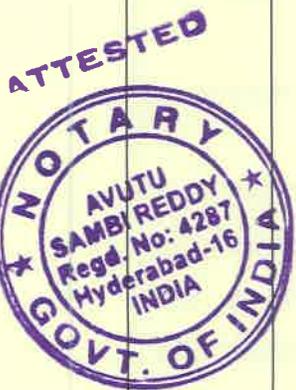
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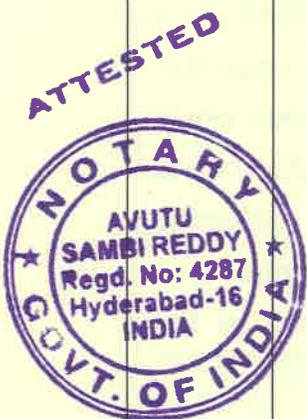
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	<p>duly intimated to the committee during their inspection. Hence, by no extent of imagination can the residues of antibiotics or any harmful substances settle due to industrial discharge by the Answering Respondent. It is reiterated at the cost of repetition that, the Answering Respondent has undertaken to adhere to and follow a standard treatment process which will be environmentally viable and safe and would not bring any harm to the surrounding environment which includes the sea water or any species therein.</p>
<p>21</p>	<p>(i) With respect to paragraph 21, the averments made by the 6th Respondent are misleading, incorrect and misrepresent the true factual scenario and the 6th Respondent is put to strict proof of the same. It is submitted that there is no agricultural crop located around 5kms near to the proposed unit belonging to the Answering Respondent. It is reiterated at the cost of repetition that the proposed area is a part of the new notified industrial corridors i.e. (i) Chennai Bangalore industrial corridor and (ii) Vishakhapatnam Chennai industrial corridor. Therefore it is completely misconstrued to state that the proposed area is not part of the notified industrial area and the allegation made is vehemently denied. In addition to this, it is submitted that the proposed area belonging to the Answering Respondent is surrounded by 4 announced industrial projects as under:</p> <ul style="list-style-type: none"> (i) Navayuga Pharma City; (ii) North Krishnapatnam Industrial Project approved and announced by Government of India and Government of Andhra Pradesh through Andhra Pradesh Industrial Infrastructure Corporation; (iii) Also recently the Government of Andhra Pradesh and State Investment Promotion Board ('SIPB') announced and approved setting up a Steel Plant; and (iv) Another Pharma unit (Potluri Pharma) is in the process of obtaining Environmental Clearance for setting up its manufacturing unit. <p>(ii) Further, it is submitted that three hatcheries are located about 3km away from the proposed area, out of which only one is operation, the other is rarely operating and the last is non-operational. Further, about 14 other hatcheries are located more than 12-15 kms away from the proposed area. it is submitted that the core operational activities of the Answering Respondent would not hamper or cause any adverse effect to the aqua culture or its revenue. It is reiterated repeatedly that the Answering Respondent will function in compliance with all prescribed and applicable statutory norms and standards as prescribed by the</p>



	<p>Government pertaining but not limited to waste management handling and discharge of treated effluents. The effluents will be treated in a diversified manner to ensure that they adhere to the standards prescribed by the 5th Respondent and are not directly discharged.</p> <p>(iii) Therefore, the averments made by the 6th Respondent that any such industrial discharge into the sea will have adverse effects on the environment, is misconceived and hence denied. Re-emphasis is placed on the fact that hazardous waste i.e. solid waste will not be disposed into the sea at any instance or cost. Such waste shall be duly sent to TSD/ co-processors/ recyclers/ authorised vendors as explained in the preceding submissions.</p>
<p>22</p>	<p>(i) With respect to paragraph 22, it is submitted that the averments are made wholly without any basis and are unsustainable in light of law. It is trite in law that a responsible statutory authority like the 6th Respondent ought not to make general academic observations without specific reference to the project in question and then conveniently tie it down to the proposed unit of the Answering Respondent, when none of the claims and positions set out in the general averments have anything to do with the proposed unit of the Answering Respondent.</p> <p>(ii) It is submitted that, for the proposed manufacturing unit, Environmental Impact Assessment (EIA) studies were duly carried out by</p> <ul style="list-style-type: none"> (i) M/s Ramky Enviro Services Pvt Ltd., an accredited EIA consultant by National Accreditation Board for Education and Training (NABET); (ii) Quality Council of India (QCI); (iii) MoEF&CC and Marine EIA Studies carried out by Indomer Hydraulics (P) Limited, Chennai which is an empanelled accredited body of the MOEF&CC along with Indian Remote Sensing (IRS); (iv) Anna University, Chennai as an authorised agency of Ministry of Environment; (v) Forests and Climate Change for demarcation of CRZ area including HTL, LTL duly superimposing the activities on the map of approved CZMP who examined the environmental and social impacts and proposed the mitigation measures for identified impacts.

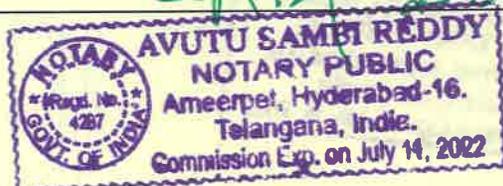


(iii) All the reports have been submitted to SEAC, SEIAA, APCZMA and the 5th Respondent who laid down the standard Environment safety norms. All requisite documents were duly and thoroughly examined carefully by all the appropriate authorities, who subsequently issued the Environmental Clearance, CRZ NOC and CFE for laying of marine outfall facility to discharge treated effluent for the proposed Manufacturing Unit.

(iv) It is pertinent to note that, all the team members who were involved in Terrestrial EIA and Marine EIA Studies are highly trained professional who hold Post Graduations and PhDs in specialized subjects like, Environmental Emission Experts (Air, Water and Solid Waste), Ecology and Biodiversity Experts, Risk Assessment and Hazardous Management, Hydrogeology expert, etc.,

Committee members of APCZMA : (2020 – 2023)

- a. Special Chief Secretary to Government (or) Principal Secretary to Government, Environment, Forest, Science and Technology Department, Govt. of AP;
- b. Principal Secretary to Government (or) Special Commissioner (Disaster Management), Revenue (Disaster Management) Department, Govt. of AP;
- c. Principal Secretary to Government (or) Commissioner of Fisheries, Fisheries Department, Govt of AP;
- d. Principal Secretary to Government (or) Commissioner of Industries, Industries and Commerce Department, Govt. of AP;
- e. Head/Director, Andhra Pradesh Space Applications Centre
- f. (APSAC), Govt of AP;
- g. Shri. Kalluri Hanumantha Rao, Scientist 'G' and Group Director, Oceanography (Retired) Andhra Pradesh Space Application Centre;
- h. Prof. Ummey Shammem, Professor, Department of Zoology, Andhra Pradesh University;
- i. Dr. P.V.N. Rao, Scientist 'H' and Deputy Director Remote Sensing Application Area (RSAA), National Remote Sensing Centre (NRSC) (Indian Space Research Organisation), Department of Space, Government of India;
- j. Dr. Shaik Basha, Senior Principal Scientist and Head, Council of Scientific and Industrial Research (CSIR) - National Environmental Engineering Research Institute (NEERI);
- k. Dr. T. Byragi Reddy, Professor, Department of Environmental Sciences, Andhra Pradesh University;
- l. Dr. Deepak Amban Mishra, Faculty Member, Indian Institute of Petroleum and Energy (IIFE);



m. Dr. S. Venkata Mohan, Senior Principal Scientist, Department of Energy and Environmental Engineering, Council of Scientific and Industrial Research (CSIR) - Indian Institute of Chemical Technology (IICT);

n. Dharitri Rakshitha Samithi, Kakinada (NGO);

o. Member Secretary, Andhra Pradesh Pollution Control Board.

Committee members of SEIAA: (2017 – 2021)

a. Sri Sarasa Balasubramanyam, Indian Administrative Service, (Retired);

b. Dr. Smt. Padma Sree Ravi, Professor, Department of Chemical Engineering, Andhra University College of Engineering (A);

c. Special Secretary/Additional Secretary, Environment, Forests, Science and Technology Department, Government of Andhra Pradesh.

Committee Member of SEAC: (2017-2021)

a. Prof. Baghavathula Venkata Sandeep, Head Department of Technology & Co-ordinator, Department of Food, Nutrition and Dietetics, College of Science and Technology, Andhra University;

b. Prof. Muvva Vijayalakshmi, Dean, Research and Development, Chairperson, Post Graduate Board of Studies in Botany and Microbiology, Department of Botany and Microbiology, Acharya Nagarjuna University.

c. Dr. Pulipati King, Department of Chemical Engineering, A.U. College of Engineering (A), Andhra University;

d. Dr. Seepana Bala Prasad, Professor, Department of Civil Engineering, A.U. College of Engineering (A), Andhra University;

e. Prof. Patruni Jagannadha Rao Department of Civil Engineering, A.U. College of Engineering (A), Andhra University;

f. Prof. Kameswara Rao, Department of Environmental Science, Andhra University;

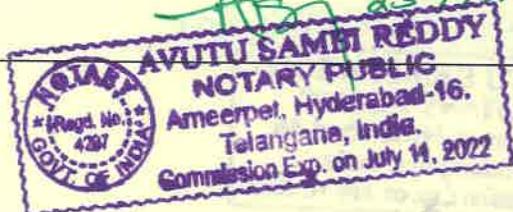
g. Prof. KVSG Murali Krishna, University College of Engineering, Jawaharlal Nehru Technological University;

h. Dr. Devala Rao Garikapati, Prof. and Principal;

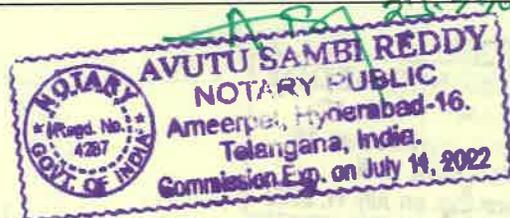
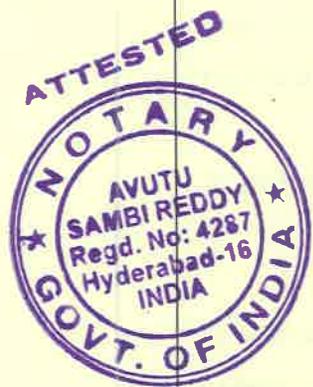
i. Dr. M. Bullaiah, Indian Forest Service (Retired);

j. Prof. Seshaiiah Kalluru, Chairman Board of Studies, Department of Chemistry, Sri Venkateswara University;

k. Dr. V.S.R.K Prasad, Visakhapatnam - 530 017, Andhra Pradesh



	<p>(v) Further, as submitted above, the proposed area is a part of the new notified industrial corridors and the North Krishnapatnam Industrial Project has been approved and announced by Government of India and Government of Andhra Pradesh through Andhra Pradesh Industrial Infrastructure Corporation. Further, recently the Government of Andhra Pradesh and State Investment Promotion Board ('SIPB') announced and approved setting up a Steel Plant in the proposed area.</p> <p>(vi) As undertaken multiple times, the 7th Respondent shall comply with all the conditions stipulated by SEIAA/SEAC in Environmental Clearance, APPCB in CFE/CFO, APCZMA in CRZ NOC, General Conditions and Industrial environmental Standards issued from time to time by CPCB and MoEF&CC therefore the proposed unit shall not create any negative impacts to the surroundings and would in fact benefit the country's economy, health infrastructure and generate employment opportunities. In light of the above submissions, where the Answering Respondent is in compliance with every letter of the Statute, the impugned Application and the Counter of the 6th Respondent is premature and needs to be dismissed <i>in limine</i>.</p>
23	<p>(i) In so far as the relief prayed for in I is concerned, it is submitted that the prayer is vague and is conveniently moulded in order to apply it to the facts of the present case and thus is baseless and bereft of any merit and logical reasoning. It is pertinent to note that, the conclusions set forth have no relation to the facts specific to the proposed manufacturing unit. The Answering Respondent is strictly in adherence to all norms prescribed under the Statutes applicable and has obtained all necessary permissions from the appropriate authorities. The 6th Respondent has merely made bald and fabricated allegations without advancing an iota of relevant evidence on how the activities of the Answering Respondent will adversely affect the environment. As substantiated above, the Answering Respondent has undertaken every measure to ensure proper and authorised discharge of their waste in light of law.</p> <p>(ii) In so far as Prayer "II" is concerned, as submitted above, the CFE(NOC) has been granted by the 5th Respondent only after detailed scrutiny of the application made by the Answering Respondent, verification report of the Regional officer- Nellore, recommendations of the CFE Committee and careful evaluation of the environmental and ecological relevance of the proposed area. Such NOC has been granted subject to the strict adherence of</p>



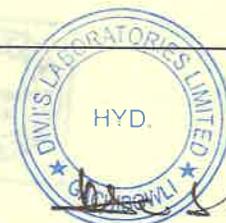
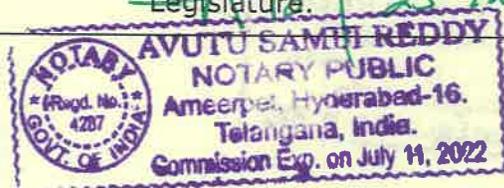
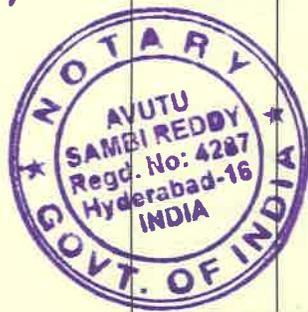
required norms and procedures as laid out in the Annexure to the CFE (NOC) order. It is further submitted that the representations of the Applicant were duly examined by the CFE Committee, APCZMA, SEAC and SEIAA, who laid down standard safety norms and precautions which are to be adhered by the Answering Respondent. It is re-emphasised that the Answering Respondent has provided assurance that it shall strictly adhere to all the prescribed safety and standard norms approved by the 5th Respondent. It is submitted that the treated effluents would be stored in guard ponds which are duly facilitated with a lock and seal system in accordance with the norms prescribed by the 5th Respondent. The effluents will be treated in a diversified manner to ensure that they adhere to the standards prescribed by the 5th Respondent and are not directly discharged. The whole activity pertaining to discharge of the treated effluents would be done only in the presence of the officials of 5th Respondent, after receiving the necessary conformation based on treatments and standards prescribed by them.

(iii) With respondent to Prayer "III", it is reiterated at the cost of repetition that the proposed area is a part of the new notified industrial corridors i.e. (i) Chennai Bangalore industrial corridor and (ii) Vishakhapatnam Chennai industrial corridor. Therefore it is completely misconstrued to state that the proposed area is a sensitive area for agricultural fields when in reality, the notified area is notified as an industrial area, and the allegation made is vehemently denied. In addition to this, it is submitted that the proposed area belonging to the Answering Respondent is surrounded by 4 announced industrial projects as under:

- (i) Navayuga Pharma City;
- (ii) North Krishnapatnam Industrial Project approved and announced by Government of India and Government of Andhra Pradesh through Andhra Pradesh Industrial Infrastructure Corporation;
- (iii) Also recently the Government of Andhra Pradesh and State Investment Promotion Board ('SIPB') announced and approved setting up a Steel Plant; and
- (iv) Another Pharma unit (Potluri Pharma) is in the process of obtaining Environmental Clearance for setting up its manufacturing unit.
- (v) Further, the prayer is a policy matter and the same needs to be addressed by the concerned regulatory body/

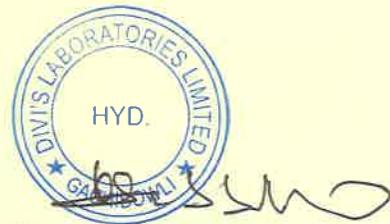
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(iv) In so far as Prayer "IV" is concerned, the Answering Respondent states that an expert committee has already reviewed the proposal and therefore a statement of this nature by the Respondent which appears altruistic is in fact irrelevant so far as this project is concerned. The 6th Respondent by such statements appears to suggest as if the regulatory mechanism as also the high level committees and approval processes set out in law are flawed. There is no basis to make such a broad claim. As already pointed out, the 6th Respondent authority is tasked with important functions, specific to the area of aquaculture and these activities are causing substantial impact due to the practises adopted and have in fact been subject-matter of several corrective actions by both this Hon'ble Tribunal and the Hon'ble Supreme Court. The authority may have to more closely scrutinise the activities within its purview.

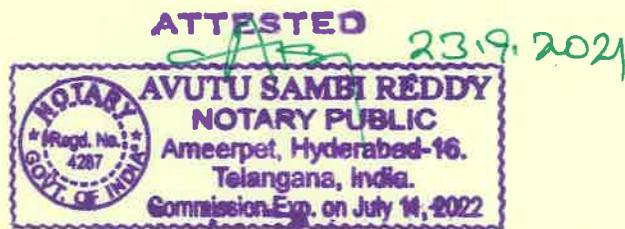
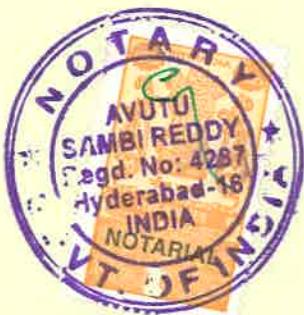
It is therefore, humbly prayed that this Hon'ble Tribunal may dismiss the Application with costs, and pass such order/orders as this Tribunal may deem fit and proper in the facts and circumstances of the case and thus render justice.



Solemnly affirmed at _____ on this day of September 2021 and signed his name in my presence.

BEFORE ME

ADVOCATE



**BEFORE THE NATIONAL GREEN
TRIBUNAL SOUTHERN ZONE,
CHENNAI**

O.A No. 126 of 2021

M/s. Sri Mahalakshmi

Hatcheries ..Applicant

Versus

Union Of India

& Others ..Respondents

**REPLY OF RESPONDENT NO 7
TO COUNTER FILED BY
RESPONDENT NO 6**

M/s. R Parthasarathy

Rahul Balaji

Madhan Babu

Vishnu Mohan &

Rangasaran Mohan

COUNSEL FOR RESPONDENT NO.7