

**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

..Applicant

Versus

Union Of India & Others

..Respondents

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NO. 7**

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Dated at Chennai on this the 29th Day of September 2021.

J. J. J.

COUNSEL FOR RESPONDENT NO.7

WARNING LETTER**Divi's Laboratories Ltd. (Unit II)****MARCS-CMS 518434 – APRIL 13, 2017****Recipient:**

Mr. Kiran Divi
Divi's Laboratories Ltd. (Unit II)
Chippada Village, Annavaram
Bheemunipatnam Mandal
Andhra Pradesh 531163
India

Issuing Office:

Center for Drug Evaluation and Research
United States



10903 New Hampshire Avenue
Silver Spring, MD 20993

Via UPS**Warning Letter 320-17-34**

April 13, 2017

Mr. Kiran S. Divi
Director and President of Operations
Divi's Laboratories Ltd. (Unit II)
Unit-2, Chippada Village
Annaram Post Bheemunipatnam Mandal
Visakhapatnam District
Andhra Pradesh 531162
India

Dear Mr. Divi:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Divi's Laboratories Ltd. (Unit II) at Unit-2, Chippada Village, Visakhapatnam District, from November 29 to December 6, 2016.

This warning letter summarizes significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

Additionally, our investigators documented that your firm limited and/or refused an FDA inspection. Under the FD&C Act, as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), section 707, 21 U.S.C. 351(j), your drugs are adulterated in that they have been manufactured, processed, packed, or held in an establishment where the owner or operator has limited inspection and/or refused inspection.

We reviewed your December 24, 2016, response in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigators observed specific deviations including, but not limited to, the following.

1. Failure to ensure that test procedures are scientifically sound and appropriate to ensure that your API conform to established standards of quality and/or purity.

Our investigators observed that the software you use to conduct high performance liquid chromatography (HPLC) analyses of API for unknown impurities is configured to permit extensive use of the "inhibit integration" function without scientific justification. For example, our investigator reviewed the integration parameters you used for HPLC identification of impurities in release testing for (b)(4). These parameters demonstrated that your software was set to inhibit peak integration at four different time periods throughout the analysis. Similarly, in the impurities release testing you performed for (b)(4), your HPLC parameters were set to inhibit integration at four different time periods throughout the analysis.

Inhibiting integration at various points during release testing for commercial batches is not scientifically justified. It can mask identification and quantitation of impurities in your API, which may result in releasing API that do not conform to specifications.

In your response, you stated that you have made several corrective actions, including updating your procedure *Peak Integration Techniques for Chromatography* to include controls on the use of inhibit integration events. However, your response is inadequate in that it did not provide specific corrective action or supportive documentation for each drug's chromatographic processing parameters, including API not cited on Form FDA 483. You have not shown how you will ensure that your test methods are appropriate to determine whether your API conform to established standards and specifications. Consequently, the summary data you provided does not demonstrate that previously released lots do not contain excessive levels of unknown impurities.

In response to this letter, provide updated analyses of all lots within expiry that take into account any changes to specific test methods and chromatographic parameters.

2. Failure to prevent unauthorized access or changes to data and failure to provide adequate controls to prevent manipulation and omission of data.

During the inspection, our investigators discovered a lack of basic laboratory controls to prevent changes to and deletions from your firm's electronically-stored data in laboratories where you conduct CGMP activities. Specifically, audit trail functionality for some systems you used to conduct CGMP operations was enabled only the day before the inspection, and there were no quality unit procedures in place to review and evaluate the audit trail data. For example, you used standalone HPLC (2-RD HP/SM/32) to conduct analyses for Drug Master File (DMF) submissions and investigations, such as characterization of a starting material for your (b)(4) DMF. You also used uncontrolled systems to conduct out-of-specification (OOS) investigations for in-process materials used to manufacture (b)(4) API.

We acknowledge the corrective actions described in your response, including enabling audit trail functionality for all chromatographic systems in your laboratories, as well as procedural updates that require review and evaluation of the data generated by these systems. However, your response did not demonstrate how the specific controls you have implemented prevent deletion or alteration of data, nor have you shown how you will ensure that these controls are documented, implemented, and followed.

3. Limiting access to or copying of records

Your firm limited access to or copying of records that our investigators were entitled to inspect. For example, our investigators requested records of your audit trail data from all chromatographic systems used to test drugs for the U.S. market at your facility. The files you ultimately provided (in the form of Excel spreadsheets rather than direct exports from your chromatographic software) were not the original records or true copies, and showed signs of manipulation. The records you did provide contained highlighting, used inconsistent date formats, and lacked timestamp data; these features are inconsistent with original data directly exported from chromatographic testing software.

Our investigators and their supervisor explained at least twice that the data you provided was not representative of actual audit trail data from the chromatographic systems, and requested that you provide the original, unmodified records. Your firm stated, without reasonable explanation, that you could not provide the requested audit trail records. When our investigators explained that your failure to provide the requested records would be documented as a refusal, you acknowledged the refusal.

Our investigators documented other instances in which your firm limited the inspection by providing some, but not all, of the records requested by the FDA investigator that FDA had authority to inspect. At multiple times during the inspection, FDA requested records of CGMP activities performed in your R&D laboratories at the behest of your quality unit. However, you limited the inspection by providing only a subset

of the requested records, and our investigators also found at least one of the requested records shredded in the trash. Finally, our investigators requested chromatograms to substantiate your claim that you had identified and quantitated the impurities in (b)(4), but you never provided the records that our investigators asked for to support your claim.

When an owner, operator, or agent delays, denies, limits, or refuses an inspection, the drugs may be deemed adulterated under section 501(j) of the FD&C Act. See FDA's guidance document, *Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection*, at [https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM360484.pdf \(/media/86328/download\)](https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM360484.pdf (/media/86328/download)).

Data Integrity Remediation

Your quality system does not adequately ensure the accuracy and integrity of data to support the safety, effectiveness, and quality of the drugs you manufacture. We acknowledge that you are using a consultant to audit your operation and assist in meeting FDA requirements.

In response to this letter, provide the following.

- A. A comprehensive investigation into the extent of the inaccuracies in data records and reporting. Your investigation should include:
- A detailed investigation protocol and methodology; a summary of all laboratories, manufacturing operations, and systems to be covered by the assessment; and a justification for any part of your operation that you propose to exclude.
 - Interviews of current and former employees to identify the nature, scope, and root cause of data inaccuracies. We recommend that these interviews be conducted by a qualified third party.
 - An assessment of the extent of data integrity deficiencies at your facility. Identify omissions, alterations, deletions, record destruction, non-contemporaneous record completion, and other deficiencies. Describe all parts of your facility's operations in which you discovered data integrity lapses.
 - A comprehensive retrospective evaluation of the nature of the testing data integrity deficiencies. We recommend that a qualified third party with specific expertise in the area where potential breaches were identified should evaluate all data integrity lapses.
- B. A current risk assessment of the potential effects of the observed failures on the quality of your drugs. Your assessment should include analyses of the risks to patients caused by the release of drugs affected by a lapse of data integrity, and risks posed by ongoing operations.
- C. A management strategy for your firm that includes the details of your global corrective action and preventive action plan. Your strategy should include:
- A detailed corrective action plan that describes how you intend to ensure the reliability and completeness of all of the data you generate, including analytical data, manufacturing records, and all data submitted to FDA.
 - A comprehensive description of the root causes of your data integrity lapses, including evidence that the scope and depth of the current action plan is commensurate with the findings of the investigation and risk assessment. Indicate whether individuals responsible for data integrity lapses remain able to influence CGMP-related or drug application data at your firm.
 - Interim measures describing the actions you have taken or will take to protect patients and to ensure the quality of your drugs, such as notifying your customers, recalling product, conducting additional testing, adding lots to your stability programs to assure stability, drug application actions, and enhanced complaint monitoring.
 - Long-term measures describing any remediation efforts and enhancements to procedures, processes, methods, controls, systems, management oversight, and human resources (e.g., training, staffing improvements) designed to ensure the integrity of your company's data.
 - A status report for any of the above activities already underway or completed.

FDA considers the expectations outlined in ICH Q7 in determining whether API are manufactured in conformance with CGMP. See FDA's guidance document, *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients*, for guidance regarding CGMP for the manufacture of API, at [https://www.fda.gov/downloads/Drugs/.../Guidances/ucm073497.pdf \(/media/71518/download\)](https://www.fda.gov/downloads/Drugs/.../Guidances/ucm073497.pdf (/media/71518/download)).

You are required to submit any addition, deletion, or other change to your Drug Master File to the FDA under 21 CFR 314.420. You are also required to notify each person authorized to reference the information in the DMF about pertinent changes. Failure to annually update the DMF

can cause delays to FDA's review of pending applications, and may result in FDA initiating proceedings to close the DMF.

Conclusion

Deviations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these deviations, for determining the causes, for preventing their recurrence, and for preventing other deviations in your facility.

If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov, so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b) and allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

FDA placed your firm on Import Alert 66-40 and 99-32 on March 20, 2017.

Until you correct all deviations completely and we confirm your compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug manufacturer.

Failure to correct these deviations may also result in FDA continuing to refuse admission of articles manufactured at Divi's Laboratories Ltd. (Unit II) at Unit-2, Chippada Village, Visakhapatnam District into the United States under section 801(a)(3) of the FD&C Act, 21 U.S.C. 381(a)(3). Under the same authority, articles may be subject to refusal of admission, in that the methods and controls used in their manufacture do not appear to conform to CGMP within the meaning of section 501(a)(2)(B) of the FD&C Act, 21 U.S.C. 351(a)(2)(B).

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your deviations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov (<mailto:CDER-OC-OMQ-Communications@fda.hhs.gov>) or mail your reply to:

Marisa Heayn
Consumer Safety Officer
U.S. Food and Drug Administration
White Oak Building 51, Room 4359
10903 New Hampshire Avenue
Silver Spring, MD 20993
USA

Please identify your response with FEI 3004149463.

Sincerely,

/S/

Thomas J. Cosgrove, J.D.

Director

Office of Manufacturing Quality

Office of Compliance

Center for Drug Evaluation and Research

Close Out Letter

- [Divi's Laboratories Ltd. \(Unit II\) - Close Out Letter 11/7/17 \(/ucm584408\)](#)

[More Warning Letters \(/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters\)](#)

Divi's Laboratories Ltd. (Unit II) - Close Out Letter 11/7/17



10903 New Hampshire Avenue
Silver Spring, MD 20993

November 7, 2017

Mr. Kiran Divi
Director and President Operations
Divi's Laboratories Ltd. (Unit 11)
Chippada Village, Annavaram
Bheemunipatnam Mandal
Visakhapatnam District
Andhra Pradesh, 531163 India

Reference: FEI 3004149463

Dear Mr. Divi:

The Food and Drug Administration (FDA) has completed an evaluation of your firm's corrective actions in response to our Warning Letter: 320-17-34 dated April 13, 2017. Based on our evaluation, it appears that you have addressed the deviations contained in this Warning Letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections.

This letter does not pertain to CDER/OPQ, CDER/OND, or CDER/OGD decision-making on any pending applications naming this facility and is without prejudice to future decisions by those offices relating to such applications.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The FDA expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should deviations be observed during a subsequent inspection or through other means.

Sincerely,
/S/

Marisa Heayn
Compliance Officer
Division of Drug Quality II

More in 2017
(/ICECI/EnforcementActions/WarningLetters/2017/default.htm)



Divi's Laboratories Limited

November 15, 2017

To
The Secretary
National Stock Exchange of India Limited
Exchange Plaza,
Bandra-Kurla Complex, Bandra (East)
MUMBAI – 400 051

Stock Code: DIVISLAB

To
The Secretary
BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street
MUMBAI – 400 001

Stock Code: 532488

Dear Sir/ Madam,

Sub: Update on lifting of Import Alert 66-40 by US-FDA

We had earlier informed the Exchanges vide our letter of 2nd November, 2017 that the US-FDA will be lifting the Import Alert 66-40 imposed on the company's Unit-II at Visakhapatnam.

The FDA's website has now been updated on 14th November, 2017 and the Import Alert 66-40 on the company's Unit-II has been removed.

This for your kind information and record.

Thanking you,

Yours faithfully
For **Divi's Laboratories Limited**


P.V. Lakshmi Rajani
Company Secretary



“An ISO-9001, ISO-14001 and OHSAS-18001 Triple certified company”

Regd. Off. : Divi Towers, 1-72/23(P)/DIVIS/303, Cyber Hills, Gachibowli, Hyderabad - 500 032, Telangana, INDIA.

Tel : 91-40-2378 6300, Fax : 91-40-2378 6460, CIN : L24110TG1990PLC011854

E-mail : mail@divislaboratories.com, Website : www.divislaboratories.com



भारत का राजपत्र The Gazette of India

असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (ii)

PART II—Section 3—Sub-section (ii)

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

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नई दिल्ली, शुक्रवार, दिसम्बर 22, 2017/पौष 1, 1939

No. 3500]

NEW DELHI, FRIDAY, DECEMBER 22, 2017/PAUSA 1, 1939

पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय

अधिसूचना

नई दिल्ली, 20 दिसम्बर, 2017

का.आ. 4001(अ).—केन्द्रीय सरकार, पर्यावरण (संरक्षण) अधिनियम, 1986 (1986 का 29) की धारा 3 की उपधारा (3) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए और भारत सरकार के तत्कालीन पर्यावरण और वन मंत्रालय की अधिसूचना संख्यांक का. आ. 1533(अ), तारीख 14 सितम्बर, 2006 (जिसे इसमें इसके पश्चात् उक्त राजपत्र अधिसूचना कहा गया है) के अनुसरण में राज्यक्षेत्र स्तरीय पर्यावरण समाघात निर्धारण प्राधिकरण, आंध्र प्रदेश (जिसे इसमें इसके पश्चात् प्राधिकरण, आंध्र प्रदेश कहा गया है) का गठन करती है, जिसमें निम्नलिखित तीन सदस्य होंगे, अर्थात् :-

1. श्री सरासा बालासुब्रह्मणियम, -- अध्यक्ष
भारतीय प्रशासनिक सेवा (सेवानिवृत्त),
कमरा सं. 209-212, पहला तल, एल-ब्लॉक,
आं.प्र. सचिवालय भवन, सैफाबाद,
हैदराबाद – 500 022, आंध्र प्रदेश ।
2. डॉ. श्रीमती पदमा श्री रवि, -- सदस्य
प्रोफेसर,
रसायन इंजीनियरी विभाग,
आंध्र प्रदेश इंजीनियरी महाविद्यालय (अ),
विशाखापट्टनम – 530 003, आंध्र प्रदेश ।
3. विशेष सचिव, /अपर सचिव, -- सदस्य-सचिव
पर्यावरण, वन, विज्ञान और प्रौद्योगिकी विभाग,
आंध्र प्रदेश सरकार ।

2. प्राधिकरण, आंध्र प्रदेश का अध्यक्ष और सदस्य राजपत्र में इस आदेश के प्रकाशन की तारीख से तीन वर्ष की अवधि के लिए पद धारण करेंगे।
3. प्राधिकरण, आंध्र प्रदेश ऐसी शक्तियों का प्रयोग करेगा और ऐसी प्रक्रियाओं का अनुपालन करेगा जो उक्त अधिसूचना में प्रगणित हों।
4. प्राधिकरण, आंध्र प्रदेश अपने विनिश्चय, पैरा 5 के अधीन गठित राज्य स्तरीय विशेषज्ञ मूल्यांकन समितियों की सिफारिशों के पश्चात् करेगा।
5. केन्द्रीय सरकार, प्राधिकरण, आंध्र प्रदेश की सहायता करने के लिए आंध्र प्रदेश राज्य सरकार के परामर्श से राज्य विशेषज्ञ मूल्यांकन समिति (जिसे इसमें इसके पश्चात् राज्य विशेषज्ञ मूल्यांकन समिति, आंध्र प्रदेश कहा गया है) का गठन करती है, जिसमें निम्नलिखित सदस्य होंगे, अर्थात् :--

1. डॉ. वी.एस.आर.के. प्रसाद, - अध्यक्ष ;
प्रशांती नगर, प्लॉट नं. 28,
द्वार संख्या 8-4-53, पेडवाल्टियर,
विशाखापत्तनम - 530 017, आंध्र प्रदेश
2. प्रो. मुन्वा विजयालक्ष्मी, - सदस्य ;
डीन, अनुसंधान और विकास,
अध्यक्ष, वनस्पति विज्ञान और सूक्ष्म जीव विज्ञान, वनस्पति विज्ञान तथा सूक्ष्म जीव
विज्ञान विभाग स्नातकोत्तर अध्ययन बोर्ड,
आचार्य नागार्जुन विश्वविद्यालय,
नागार्जुन नगर, गुंटूर -522 510, आंध्र प्रदेश
3. डॉ. पुलिपति किंग, - सदस्य ;
रसायन इंजीनियरी विभाग,
एयू कॉलेज ऑफ इंजीनियरिंग (ए), आंध्र विश्वविद्यालय,
विशाखापत्तनम - 530 003, आंध्र प्रदेश
4. डॉ. देवला राव गारिकापति, - सदस्य ;
प्रोफेसर और प्रिंसिपल,
मकान सं. 2-99 / 1, कोटेवरी स्टेशन, तीसरा क्रॉस,
रमावरापट्टु - 521 108, विजयवाड़ा ग्रामीण कृष्णा (जिला),
आंध्र प्रदेश
5. डॉ. सीपना बाला प्रसाद, - सदस्य ;
प्रोफेसर, सिविल इंजीनियरिंग विभाग,
एयू कॉलेज ऑफ इंजीनियरिंग (ए), आंध्र विश्वविद्यालय,
विशाखापत्तनम -530 003, आंध्र प्रदेश
6. प्रो. सेशाय्या कालस, - सदस्य ;
अध्यक्ष, अध्ययन बोर्ड,
रसायन विज्ञान विभाग,
श्री वेंकटेश्वर विश्वविद्यालय,

- तिरुपति -517 502, आंध्र प्रदेश
7. प्रो. बागवथुला वेंकट संदीप, - सदस्य ;
प्रभारी, प्रौद्योगिकी विभाग और
समन्वयक, खाद्य, पोषण और आहारशास्त्र विभाग,
कॉलेज ऑफ साइंस एंड टेक्नोलॉजी, आंध्र विश्वविद्यालय,
विशाखापत्तनम -530003, आंध्र प्रदेश
8. प्रो. केवीएसजी मुरली कृष्ण, - सदस्य ;
यूनिवर्सिटी कॉलेज ऑफ इंजीनियरिंग,
जवाहरलाल नेहरू प्रौद्योगिकी विश्वविद्यालय,
काकीनाडा -533 003, आंध्र प्रदेश
9. प्रो. बी. कोंडाला राव, - सदस्य ;
प्रोफेसर और अध्यक्ष, बीओएस (सेवानिवृत्त)
4-61-12/1 लॉसन बे कॉलोनी,
विशाखापत्तनम - 530 017, आंध्र प्रदेश
10. प्रो. पतरूणी जगन्नाथ राव, - सदस्य ;
सिविल इंजीनियरिंग विभाग,
एयू कॉलेज ऑफ इंजीनियरिंग (ए),
आंध्र विश्वविद्यालय, विशाखापत्तनम -530 003, आंध्र प्रदेश
11. प्रो. कामेस्वर राव, - सदस्य ;
पर्यावरण विज्ञान विभाग, आंध्र विश्वविद्यालय,
विशाखापत्तनम - 530 003, आंध्र प्रदेश
12. श्री विसाप्रागडे वेद कुमार, - सदस्य ;
फ्लैट नंबर 403, मैक एन्क्लेव,
शारदा विद्या निकेतन के सामने,
ओम नगर, लंगर हाउस, गोलकोंडा (पीओ),
हैदराबाद -500008, तेलंगाना
13. डॉ. एम. बुल्लायहा, - सदस्य ;
भारतीय वन सेवा (सेवानिवृत्त)
फ्लैट नंबर 203 लक्ष्मी अपार्टमेंट,
स्ट्रीट नं. 7 मस्जिद रोड, विद्यानगर,
हैदराबाद -500 044, तेलंगाना
14. सदस्य सचिव, - सचिव ।
आंध्र प्रदेश प्रदूषण नियंत्रण बोर्ड, प्रधान अधिकारी,
एपीपीसीबी, विजयवाड़ा -520 010, आंध्र प्रदेश

6. राज्य विशेषज्ञ मूल्यांकन समिति, आंध्र प्रदेश के अध्यक्ष और सदस्य राजपत्र में इस आदेश के प्रकाशन की तारीख से तीन वर्ष की अवधि के लिए पद धारण करेंगे।
7. राज्य विशेषज्ञ मूल्यांकन समिति, आंध्र प्रदेश ऐसी शक्तियों का प्रयोग करेगी और ऐसी प्रक्रियाओं का अनुपालन करेगी, जो उक्त अधिसूचना में प्रगणित किया जाए।
8. राज्य विशेषज्ञ मूल्यांकन समिति, आंध्र प्रदेश सामूहिक उत्तरदायित्व के सिद्धांत पर कार्य करेगी और अध्यक्ष प्रत्येक मामले में सर्वसम्मति पर पहुंचने का प्रयास करेगा और यदि सर्वसम्मति पर नहीं पहुंचा जा सकता है तो बहुमत का मत अभिभावी होगा।
9. आंध्र प्रदेश सरकार, प्राधिकरण, आंध्र प्रदेश और राज्य विशेषज्ञ मूल्यांकन समिति, आंध्र प्रदेश के सचिवालय के रूप में कार्य करने के लिए किसी अभिकरण को अधिसूचित करेगी और प्राधिकरण, आंध्र प्रदेश और राज्य विशेषज्ञ मूल्यांकन समिति, आंध्र प्रदेश के कानूनी कृत्यों के संबंध में सभी वित्तीय और संभार तंत्र सहायता, जिसके अंतर्गत आवास, परिवहन और ऐसी अन्य सुविधाएं हैं, उपलब्ध कराएगी।
10. प्राधिकरण, आंध्र प्रदेश और राज्य विशेषज्ञ मूल्यांकन समिति, आंध्र प्रदेश के अध्यक्ष और सदस्यों को बैठक फीस, यात्रा भत्ता और मंहगाई भत्ता आंध्र प्रदेश राज्य सरकार के नियमों के अनुसार संदेय किया जाएगा।

[फा. सं. जे-11013/36/2007-आई.ए.॥(1)]

ज्ञानेश भारती, संयुक्त सचिव

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE NOTIFICATION

New Delhi, the 20th December, 2017

S.O. 4001(E).—In exercise of the powers conferred by sub-section (3) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986) and in pursuance of the notification of the Government of India in the erstwhile Ministry of Environment and Forests, number S.O. 1533(E), dated the 14th September, 2006 (hereinafter referred to as the said Notification), the Central Government hereby constitutes the State Level Environment Impact Assessment Authority, Andhra Pradesh (hereinafter referred to as the Authority, Andhra Pradesh) comprising of the following Members, namely: -

1. Sri Sarasa Balasubramanyam, -Chairman;
Indian Administrative Service, (Retired),

Room No.209-212, 1st Floor, L-Block,
A.P. Secretariat Building, Saifabad,
Hyderabad-500 022, Andhra Pradesh
2. Dr. Smt. Padma Sree Ravi, -Member;
Professor,
Department of Chemical Engineering,
Andhra University College of Engineering (A),
Visakhapatnam – 530 003, Andhra Pradesh
3. Special Secretary/Additional Secretary, -Member Secretary.
Environment, Forests, Science and Technology Department,
Government of Andhra Pradesh

2. The Chairman and Members of the Authority, Andhra Pradesh shall hold office for a term of three years from the date of publication of this order in the Official Gazette.

3. The Authority, Andhra Pradesh shall exercise such powers and follow such procedures as enumerated in the said Notification.
4. The Authority, Andhra Pradesh shall take its decision after the recommendations of the State Level Expert Appraisal Committee (SEAC) constituted under paragraph 5.
5. To assist the Authority, Andhra Pradesh, the Central Government in consultation with the State Government of Andhra Pradesh, hereby constitutes the State Expert Appraisal Committee (SEAC) (hereinafter referred to as SEAC, Andhra Pradesh) comprising of the following Members, namely:-
 1. Dr. V.S.R.K Prasad, -Chairman;
Prasanthi Nagar, Plot No.28,
Door No.8-4-53, Pedawaltair,
Visakhapatnam - 530 017, Andhra Pradesh
 2. Prof. Muvva Vijayalakshmi, -Member;
Dean, Research and Development,
Chairperson, Post Graduate Board of Studies in Botany and Microbiology,
Department of Botany and Microbiology,
Acharya Nagarjuna University,
Nagarjuna Nagar, Guntur-522 510, Andhra Pradesh
 3. Dr. Pulipati King, -Member;
Department of Chemical Engineering,
A.U. College of Engineering (A), Andhra University, Visakhapatnam-
530 003, Andhra Pradesh
 4. Dr. Devala Rao Garikapati, -Member;
Prof. and Principal,
H.No.2-99/1, Kottevari Station, 3rd Cross, Ramavarappadu - 521 108,
Vijayawada Rural Krishna (Dist), Andhra Pradesh
 5. Dr. Seepana Bala Prasad, -Member;
Professor, Department of Civil Engineering,
A.U. College of Engineering (A), Andhra University, Visakhapatnam-
530 003, Andhra Pradesh
 6. Prof. Seshaiiah Kalluru, -Member;
Chairman Board of Studies,
Department of Chemistry,
Sri Venkateswara University,
Tirupati - 517 502, Andhra Pradesh
 7. Prof. Baghavathula Venkata Sandeep, -Member;
Head Department of Technology & Co-ordinator, Department of Food,
Nutrition and Dietetics,
College of Science and Technology, Andhra University,
Visakhapatnam- 530003, Andhra Pradesh
 8. Prof. KVSG Murali Krishna, -Member;
University College of Engineering,
Jawaharlal Nehru Technological University,
Kakinada – 533 003, Andhra Pradesh
 9. Prof. B. Kondala Rao, -Member;
Professor and Chairman, BOS (Retired),
4-61-12/1Lawson's Bay Colony,
Visakhapatnam - 530 017, Andhra Pradesh
 10. Prof. Patruni Jagannadha Rao -Member;
Department of Civil Engineering,
A.U. College of Engineering (A), Andhra University, Visakhapatnam – 530
003, Andhra Pradesh

11. Prof. Kameswara Rao, -Member;
Department of Environmental Science, Andhra University,
Visakhapatnam – 530 003, Andhra Pradesh
12. Shri Vissapragada Veda Kumar, -Member;
Flat No. 403, MAC Enclave,
Opposite Sarada Vidya Niketan,
OM Nagar, Langar House, Golkonda (PO),
Hyderabad-500008, Telangana
13. Dr. M. Bullaiah, -Member;
Indian Forest Service (Retired)
Flat No.203 Laxmi Apartment,
Street No.7 Maszid Road, Vidyanagar,
Hyderabad -500 044, Telangana
14. Member Secretary, -Secretary.
Andhra Pradesh Pollution Control Board, Head Officer, APPCB,
Vijayawada-520 010, Andhra Pradesh
6. The Chairman and Members of SEAC, Andhra Pradesh shall hold office for a term of three years from the date of publication of this order in the Official Gazette.
7. The SEAC, Andhra Pradesh shall exercise such powers and follow such procedures as enumerated in the said Notification.
8. The SEAC, Andhra Pradesh shall function on the principle of collective responsibility and its Chairman shall endeavor to reach a consensus in each case, and if consensus cannot be reached, the view of the majority shall prevail.
9. The Government of Andhra Pradesh shall notify an agency to act as Secretariat for the Authority, Andhra Pradesh and SEAC, Andhra Pradesh, and the Secretariat shall provide all financial and logistic support including accommodation, transportation and such other facilities in respect of all the statutory functions of the Authority, Andhra Pradesh and SEAC, Andhra Pradesh.
10. The sitting fee, travelling allowances and dearness allowances to the Chairman and Members of the Authority, Andhra Pradesh and SEAC, Andhra Pradesh shall be paid as per the rules of the State Government of Andhra Pradesh.

[F. No. J-11013/36/2007-IA-II (I)]

GYANESH BHARTI, Jt. Secy.



U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Via UPS
Return Receipt Requested

September 4, 2019

Dr. Murali K. Divi
Chairman & Managing Director
Divi's Laboratories Ltd. (Unit II)
Chippada Village, Annavaram, Bheemunipatnam Mandal
Visakhapatnam District,
Andhra Pradesh 531163 India

Dear Dr. Murali K. Divi:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Divi's Laboratories Ltd. (Unit II), FEI: 3004149463, located at Chippada Village, Annavaram, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh, India, from June 10 to June 15, 2019. FDA has determined that the inspection classification of this facility is "no action indicated" (NAI).¹ Based on this inspection, this facility is considered to be in an acceptable state of compliance with regard to current good manufacturing practice (CGMP).

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of NAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing applications referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by the appropriate CDER or CVM review office. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA in accordance with the Freedom of Information Act (FOIA) and 21 CFR part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact LaKeesha Foster via telephone at 240-402-6476 or email at lakesha.foster@fda.hhs.gov.

Sincerely,

Milind Ganjawala
Director
Division of Drug Quality II
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research, FDA

¹ See Inspection Classification Definitions, at <https://www.fda.gov/ICECI/Inspections/ucm223231.htm>.



भारत का राजपत्र The Gazette of India

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EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (ii)
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पर्यावरण, वन और जलवायु परिवर्तन मंत्रालय

आदेश

नई दिल्ली, 1 मई, 2020

का.आ. 1423 (अ).-- केंद्रीय सरकार, पर्यावरण (संरक्षण) अधिनियम, 1986 (1986 का 29) (जिसे इसमें इसके पश्चात् उक्त अधिनियम कहा गया है) की धारा 3 की उपधारा (1) और उपधारा (3) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, राजपत्र में इस आदेश के प्रकाशन की तारीख से तीन वर्ष की अवधि के लिए निम्नलिखित व्यक्तियों से मिलकर बने आंध्र प्रदेश तटीय जोन प्रबंध प्राधिकरण (जिसे इसमें इसके पश्चात् प्राधिकरण कहा गया है) का गठन करती है, अर्थात्:—

क्र.सं.	सदस्य	प्रास्थिति
1.	सरकार के विशेष मुख्य सचिव (या) सरकार के प्रमुख सचिव, पर्यावरण, वन, विज्ञान और तकनीकी विभाग, आंध्र प्रदेश सरकार	अध्यक्ष, पदेन ;
2.	सरकार के प्रधान सचिव या विशेष आयुक्त (आपदा प्रबंधन), राजस्व विभाग (आपदा प्रबंधन), आंध्र प्रदेश सरकार	सदस्य, पदेन ;
3.	सरकार के प्रधान सचिव या मत्स्य पालन आयुक्त, मत्स्य पालन विभाग, आंध्र प्रदेश सरकार	सदस्य, पदेन ;
4.	सरकार के प्रधान सचिव या उद्योग आयुक्त, उद्योग और वाणिज्य विभाग, आंध्र प्रदेश सरकार	सदस्य, पदेन ;

5.	प्रमुख/निदेशक, आंध्र प्रदेश स्पेस ऐप्लिकेशन सेंटर (एपीएसएसी), आंध्र प्रदेश सरकार	सदस्य, पदेन ;
6.	श्री काल्लूरी हनुमंथा राव, वैज्ञानिक 'जी' और समूह निदेशक, समुद्र विज्ञान (सेवानिवृत्त) आंध्र प्रदेश स्पेस ऐप्लिकेशन सेंटर	सदस्य, (विशेषज्ञ) ;
7.	प्रो. उमे शाम्मम, प्रोफेसर, प्राणी विज्ञान विभाग, आंध्र प्रदेश विश्वविद्यालय	सदस्य, (विशेषज्ञ) ;
8.	डा. पी.वी.एन राव, वैज्ञानिक 'एच' और उप निदेशक, रिमोट सेंसिंग ऐप्लिकेशन ऐरिया (आरएसएए), नेशनल रिमोट सेंसिंग सेंटर (एनआरएससी) (भारतीय अंतरिक्ष अनुसंधान संगठन), अंतरिक्ष विभाग, भारत सरकार	सदस्य, (विशेषज्ञ) ;
9.	डा. शैक बाशा, सीनीयर प्रिन्सीपल वैज्ञानिक और प्रमुख, वैज्ञानिक तथा औद्योगिक अनुसंधान परिषद (सीएसआईआर) – राष्ट्रीय पर्यावरण इंजीनियरिंग अनुसंधान संस्थान (एनईआईआरआई)	सदस्य, (विशेषज्ञ) ;
10.	डा. टी. ब्यारागी रेड्डी, प्रोफेसर, पर्यावरण विज्ञान विभाग, आंध्र प्रदेश विश्वविद्यालय	सदस्य, (विशेषज्ञ) ;
11.	डा. दीपक अंबन मिश्रा, संकाय सदस्य, भारतीय पेट्रोलियम और ऊर्जा संस्थान (आईआईपीई)	सदस्य, (विशेषज्ञ) ;
12.	डा. एस. वेंकटा मोहन, सीनीयर प्रिन्सीपल वैज्ञानिक, ऊर्जा और पर्यावरण इंजीनियरिंग विभाग, वैज्ञानिक तथा औद्योगिक अनुसंधान परिषद (सीएसआईआर) – राष्ट्रीय रसायन प्रौद्योगिकी संस्थान (आईआईसीटी)	सदस्य, (विशेषज्ञ) ;
13.	धारित्री रक्षिता समिति, काकीनाडा	सदस्य, गैर-सरकारी संगठन ;
14.	सदस्य सचिव, आंध्र प्रदेश प्रदूषण नियंत्रण बोर्ड	सदस्य सचिव, पदेन ।

2. प्राधिकरण का मुख्यालय गुंटूर, आंध्र प्रदेश में होगा ।

3. प्राधिकरण की बैठक के लिए गणपूर्ति, इसके सदस्यों की कुल संख्या का एक-तिहाई होगी ।

4. पदेन सदस्य से भिन्न सदस्य को, केंद्रीय सरकार द्वारा नियत मानदंडों के अनुसार भत्तों का भुगतान किया जाएगा ।

5. प्राधिकरण, आंध्र प्रदेश राज्य में तटीय पर्यावरण की क्वालिटी को संरक्षित करने और सुधारने तथा तटीय विनिमय जोन क्षेत्रों में पर्यावरणीय प्रदूषण के निवारण, उपशमन और नियंत्रण के उद्देश्यों के लिए निम्नलिखित उपाय करेगा, अर्थात्:-

(i) प्राधिकरण, परियोजना प्रस्ताव के अनुमोदन के लिए आवेदन प्राप्ति के पश्चात्, यदि वह अनुमोदित तटीय जोन प्रबंध योजना के अनुसरण में हैं और भारत सरकार के पर्यावरण और वन मंत्रालय द्वारा जारी की गई तटीय विनिमय जोन अधिसूचना संख्यांक का.आ. 19(अ), तारीख 6 जनवरी, 2011 (जिसे इसमें इसके पश्चात् उक्त अधिसूचना कहा गया है) की अपेक्षाओं के भीतर है तो उसका परीक्षण करेगा और संबद्ध प्राधिकरण को ऐसी परियोजना के अनुमोदन के लिए, जैसा कि उक्त अधिसूचना में विनिर्दिष्ट है, ऐसे आवेदन की प्राप्ति की तारीख से साठ दिन के भीतर सिफारिशें करेगा;

(ii) प्राधिकरण, उक्त अधिसूचना में विनिर्दिष्ट किए गए के अनुसार तटीय विनिमय जोन में सभी विकासात्मक क्रियाकलापों को विनियमित करेगा;

(iii) प्राधिकरण, उक्त अधिसूचना के उपबंधों का प्रवर्तन और मानीटरी के लिए उत्तरदायी होगा;

(iv) प्राधिकरण, तटीय विनियम जोन क्षेत्रों और तटीय जोन प्रबंध योजना के वर्गीकरण में परिवर्तन या उपांतरणों के लिए राज्य सरकार से प्राप्त प्रस्तावों की परीक्षा करेगा और राष्ट्रीय तटीय जोन प्रबंध प्राधिकरण को उस पर विनिर्दिष्ट सिफारिशें देगा;

(v) प्राधिकरण, उक्त अधिनियम या उसके अधीन बनाए गए नियमों के उपबंधों के अभिकथित अतिक्रमण के मामलों में जांच करेगा और उक्त अधिनियम तथा उसके अधीन बनाए गए नियमों के उपबंधों के अतिक्रमण या उल्लंघन को अंतर्वलित करने वाले मामलों का पुनर्विलोकन करेगा;

(vi) प्राधिकरण, उक्त अधिसूचना के अतिक्रमण या उल्लंघन के मामलों में स्वप्रेरणा से या किसी व्यक्ति या निकाय या संगठन द्वारा किए गए परिवाद के आधार पर जांच या पुनर्विलोकन करेगा; (vii) प्राधिकरण, उक्त अधिनियम की धारा 19 के अधीन परिवाद फाइल करने के लिए प्राधिकृत है; (viii) प्राधिकरण, उसके समक्ष तथ्यों को सत्यापित करने के लिए उक्त अधिनियम की धारा 10 के अधीन यथाअपेक्षित कार्रवाई करेगा।

6. प्राधिकरण, अपने कृत्यों में पारदर्शिता बनाए रखने के उद्देश्य के लिए एक समर्पित वेबसाइट तैयार करेगा और इसके कृत्य, जिसके अंतर्गत बैठकों में कार्यसूची, बैठकों का कार्यवृत्त, प्रत्येक बैठक में किए गए विनिश्चय, उक्त अधिसूचना के अतिक्रमण तथा उल्लंघन के मामलों में सिफारिशें और ऐसे अतिक्रमण तथा उल्लंघन पर की गई कार्रवाईयां और न्यायालय मामले जिसके अंतर्गत न्यायालयों के आदेश हैं और राज्य सरकार की अनुमोदित तटीय जोन प्रबंध योजना से संबंधित सूचना डालेगा।

7. प्राधिकरण छह माह में कम से कम एक बार अपने क्रियाकलापों की रिपोर्ट राष्ट्रीय तटीय जोन प्रबंध प्राधिकरण को भेजेगा।

[फा.सं. जे-17011/27/99-आईए-III]
अरविन्द कुमार नौटियाल, संयुक्त सचिव,

MINISTRY OF ENVIRONMENT, FOREST AND CLIMATE CHANGE

ORDER

New Delhi, the 1st May, 2020

S.O. 1423(E).—In exercise of the powers conferred by sub-sections (1) and (3) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986) (hereinafter referred to as the said Act), the Central Government hereby constitutes the Andhra Pradesh Coastal Zone Management Authority (hereinafter referred to as the Authority) consisting of the following persons, for a period of three years, with effect from the date of publication of this order in the Official Gazette, namely:—

Sl.No.	Members	Status
(1)	(2)	(3)
1.	Special Chief Secretary to Government (or) Principal Secretary to Government, Environment, Forest, Science and Technology Department, Government of Andhra Pradesh	Chairman, <i>exofficio</i> ;
2.	Principal Secretary to Government (or) Special Commissioner (Disaster Management), Revenue (Disaster Management) Department, Government of Andhra Pradesh	Member, <i>exofficio</i> ;
3.	Principal Secretary to Government (or) Commissioner of Fisheries, Fisheries Department, Government of Andhra Pradesh	Member, <i>exofficio</i> ;
4.	Principal Secretary to Government (or) Commissioner of Industries, Industries and Commerce Department, Government of Andhra Pradesh	Member, <i>exofficio</i> ;

5.	Head/Director, Andhra Pradesh Space Applications Centre (APSAC), Government of Andhra Pradesh	Member, <i>ex officio</i> ;
6.	Shri. Kalluri Hanumantha Rao, Scientist 'G' and Group Director, Oceanography (Retired) Andhra Pradesh Space Application Centre	Member, (<i>Expert</i>);
7.	Prof. Ummey Shammem, Professor, Department of Zoology, Andhra Pradesh University	Member, (<i>Expert</i>);
8.	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	Member, (<i>Expert</i>);
9.	Dr. Shaik Basha, Senior Principal Scientist and Head, Council of Scientific and Industrial Research (CSIR) - National Environmental Engineering Research Institute (NEERI)	Member, (<i>Expert</i>);
10.	Dr. T. Byragi Reddy, Professor, Department of Environmental Sciences, Andhra Pradesh University	Member, (<i>Expert</i>);
11.	Dr. Deepak Amban Mishra, Faculty Member, Indian Institute of Petroleum and Energy (IPE)	Member, (<i>Expert</i>);
12.	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)	Member, (<i>Expert</i>);
13.	Dharitri Rakshitha Samithi, Kakinada	Member, Non-Governmental Organisation;
14.	Member Secretary, Andhra Pradesh Pollution Control Board	Member Secretary, <i>ex officio</i> .

2. The Authority shall have its headquarters at Guntur, Andhra Pradesh.
3. The quorum for the meeting of the Authority shall be one-third of the total number of its Members.
4. A Member, other than an *ex officio* Member, shall be paid allowances as per the norms decided by the Central Government.
5. The Authority shall, for the purposes of protecting and improving the quality of the costal environment and preventing, abating and controlling environmental pollution in the Coastal Regulation Zone areas in the State of Andhra Pradesh, take the following measures, namely: -
 - (i) the Authority shall, after receiving the application for approval of project proposal, examine the same if it is in accordance with the approved Coastal Zone management Plan and within the requirements of the Coastal Regulation Zone notification issued by the Government of India in the erstwhile Ministry of Environment and Forests and published *vide* number S.O.19(E), dated the 6th January, 2011 (hereinafter referred to as the said notification), and make recommendations for approval of such project to the concerned authority, as specified in the said notification, within a period of sixty days from the date of receipt of such application;

- (ii) the Authority shall regulate all developmental activities in the Coastal Regulation Zone areas as specified in the said notification;
 - (iii) the Authority shall be responsible for enforcing and monitoring the provisions of the said notification;
 - (iv) the Authority shall examine the proposals received from the State Government for changes or modifications in the classification of Coastal Regulation Zone areas and in the Coastal Zone Management Plan and make specific recommendations thereon, to the National Coastal Zone Management Authority;
 - (v) the Authority shall inquire into cases of alleged violation of the provisions of the said Act or the rules made thereunder; and review the cases involving violations or contraventions of the provisions of the said Act and the rules made thereunder;
 - (vi) the Authority shall inquire or review cases of violations or contraventions of the said notification suo-moto, or on the basis of a complaint made by any individual or body or organisation;
 - (vii) the Authority is authorised to file complaints under section 19 of the said Act;
 - (viii) the Authority shall take such action as may be required under section 10 of the said Act, to verify the facts of the cases before it.
6. The Authority shall, for the purpose of maintaining transparency in its functioning, create a dedicated website and post the information relating to its functions, including the agenda in its meetings, minutes of the meetings, decisions taken in each meeting, recommendations for matters on violations and contraventions of the said notification and actions taken on such violations and contraventions, court matters including the orders of the courts and the approved Coastal Zone Management Plan of the State Government.
7. The Authority shall furnish reports of its activities at least once in six months to the National Coastal Zone Management Authority.

[F. No. J-17011/27/99-IA-III]

ARVIND KUMAR NAUTIYAL, Jt. Secy.



Divi's Laboratories Limited

Date: 30th July, 2021

DATE OF LAST FDA INSPECTION AND OUTCOME

Manufacturing Site: Divi's Laboratories Limited Unit-2, Chippada Village, Annavaram Post Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh 531162, India (IND)

FEI #: 3004149463

US FDA last inspection dates: January 27 to 31, 2020

Outcome: No FDA-483 Inspectional Observations were issued and the facility was found acceptable.

US FDA classified the inspection as NAI (No Action Indicated) and below is the screenshot of the classification from the FDA website.

District	Firm Name	City	State	Zip Code	Country / Area	Inspection End Date	Center	Project Area	Classification
ORA	Divi's Laboratories Ltd. (Unit II)	Visakhapatnam District			IN	01/31/20	CDER	Drug Quality Assurance	NAI

BPB
30/07/21

B. Ramesh Babu
Manager – QA and RA
Divi's Laboratories Limited, Unit-2.

**An ISO-9001 (QMS); ISO-14001 (EMS) and OHSAS-18001 (Health & Safety)
 Triple Certified Company**

FACTORY : Unit-2, Chippada Village, Annavaram Post, Bheemunipatnam Mandal, Visakhapatnam District, Andhra Pradesh-531 162, INDIA.
 Ph. : +91-8922-248911, Fax : +91-8922-248922.
 CORPORATE OFFICE : 1-72/23(P) / Divis / 303, Divi Towers, Cyber Hills, Gachibowli, Hyderabad-500 032, Telangana, India. CIN : L24110TG1990PLC011854
 Ph. : +91-40-23786300, 23786400, Fax : +91-40-23786460, E-mail : mail@divislaboratories.com, Website : www.divislaboratories.com

**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

**ADDITIONAL TYPED SET OF
DOCUMENTS FILED BY
RESPONDENT NO. 7**

M/s. R Parthasarathy

Rahul Balaji

Madhan Babu

Vishnu Mohan &

Rangasaran Mohan

COUNSEL FOR RESPONDENT NO.7