(187)

F. No. QA/GNL/BCN/INV-ABR/01/

Central Drugs Standard Control Organization

Directorate General of Health Services

(O/o DCG I)

FDA Bhawan, Kotla Road
New Delhi-110002

Subject: Suspension of permission / approval under Rule 122DB of Drugs and Cosmetic Rule 1945 for the drug Albupax manufactured by M/s NATCO Pharmaceutical Limited-regarding.

Reference is invited to the Ministry of Health and Family Welfare letter No. QA/GNL/BCN/INV-ABR/09 dated 23.12.2009 on the above mentioned subject.

The case under reference relates to the stay order granted by the Ministry of Health and Family Welfare to M/s NATCO Pharma Ltd., Hyderabad against the order of suspension of the new drug approval granted to M/s NATCO Pharma for manufacture of albupax and permission for initiating prosecution against the firm. Hon'ble HFM while approving the stay to the letter of DCGI dated 21.10.2009 recorded the following minutes:

"The company seems to have made allegations against the procedure followed by DCGI. I would like to know the circumstances under which DCGI recommended prosecution of the company without giving an appropriate opportunity or appeal against its order of suspension as alleged by the company. Secondly, I would like to have the data on the Action taken by DCGI against such companies in the last 2 or 3 years for the violations in similar cases under the Drugs and Cosmetics Act.

As the Company has made serious allegations against the process of testing of CDL, Kolkata, it would be advisable to conduct testing of its fresh product, after the stay order on suspension of license is implemented, at a laboratory approved under Drugs and Cosmetics Act as recommended by Secretary (HR)."

HFM has desired to know-

(1) The circumstances under which DCGI recommended prosecution of the company without giving an appropriate opportunity or appeal against its order of suspension as alleged by the company.

It is submitted that ample opportunities were provided to M/s Natco Pharma Ltd., Hyderabad at every stage for giving explanation and concrete evidences in respect of allegation made by the complainant or results of investigation before recommending actions like suspension of new drug permission and taking appropriate action including prosecution in the case of the statutory sample of the drug found to be failing in respect of endotoxin test and deficiencies detected in the manufacturing process in contravention of Schedule M and Schedule V of the D & C Act.

The present case was initiated on the basis of a complaint received from Dr. Kiran Majumdar Shaw, Chairman and Managing Director, Biocon Ltd., Bangalore and Dr. Patrick Soon- Shiong, Chairman and Chief Executive Officer, Abraxix Bio-Sciences, Los Angeles, California, USA, wherein it was stated that 'Albupax' manufactured by M/s NATCO Pharma given to cancer patients poses serious health risk as it contains high level of atleast two toxic substances that is bacterial endotoxin and chloroform well known to death or disability. It was stated that the chemical analysis have established that it is not a boanfide generic version of its innovator drug 'Abraxane'. It was further stated in the letter that Chemical Analysis establishes that Albupax manufactured by M/s NATCO Pharma is unsafe for human use and could lead to immediate death or disability. Further the complaint letter mentions that Albupax (Paclitaxel Injection) also contains undesired level of chloroform & it grows particulate matter after 8 hours of reconstitution. It also mentions that various samples of **Albupax has been analysed** at **four different laboratories including an independent Indian laboratories i.e. Sri Ram Institute of Industrial Research , Bangalore, India** and it was stated to be grossly failing in Bacterial endotoxin test, and chloroform level test. High level of endotoxin which are upto 8.5 times higher than the permissible national and international limits would create an immediate substantial risk of toxicity to any patient upon administering causing even death. The letter also mentions that high level of endotoxins have been expressly attributed to patient deaths in public health crisis that have arisen in other countries.

As the issues raised in the complaint were serious in nature, threatening life of the patients of breast cancer, immediate steps were required to be taken to stem

the problem and take urgent remedial action. The matter was required to be investigated thoroughly under the ambit of Drugs and Cosmetics Act, 1940 before taking any action.

The chronology of procedure followed in the case for investigations and opportunities offered to M/s NATCO Pharma to furnish their explanations is at **Annexure I.** and details are as following:-

As stated herein above, the case emanated from the fact that a complaint was received from Dr. Kiran Majumdar Shah of M/s. BIOCON Limited, Bangalore and Dr. Patrick Soon-Shiong, Chairman and Chief Executive Officer, Abraxix Bio-Sciences, Los Angeles, California, USA, wherein it was requested to take an urgent regulatory Action in relation to serious health risk posed by Albupax.

Considering the seriousness of the issue that the NATCO' s product poses serious public health risk because it is stated to contain high level of toxic substance, which can cause death or disability, ***the office of DCG(I), vide letter dated 30/3/2009 requested NATCO Pharma to send their comments within ten days & also depute senior representative well versed with quality/Technical issues for discussion on the subject matter on 20.4.2009 at DCGI office, New Delhi.*** Simultaneously, all Zonal & Subzonal officers vide letter dated 30/3/2009 were requested depute Drug Inspectors to draw the samples of both the drugs Albupax manufactured by Natco as well as Abraxne manufactured by Abraxis Bio-Sciences, USA for test & analysis at CDL, Kolkata. It is important to mention herein that section 22 and 23 of the Drugs and Cosmetics Act, 1940 lays down the procedures for collecting the samples of the drugs and sending it for testing to the Drugs Laboratory. Copies of both the letters dated 30/3/2009 are at **Annexure II.**

NATCO Pharma Ltd vide its letter dated 7/4/2009, replied that their product conforms to all the quality & specification which they had submitted as well as Pharmacopeia /ICH guideline. Copy of the letters dated 7/4/2009 is at **Annexure III.**

The **statutory samples** of Albupax were drawn by CDSCO, Hyderabad, Office by their respective Drug Inspector under Section 22(b) & 23 (3) & (4) of the Drugs and Cosmetics Act, 1940 and the same were sent for testing under form 18 of

the Drugs and Cosmetics Rules to Central Drugs Laboratory, Kolkatta. From CDSCO, West Zone and North Zone, **Survey samples** were collected and they were also sent for testing to the Central Drugs Laboratory, Kolkatta as per the procedures. It is important to mention here that Central Drugs Laboratory, Kolkatta (CDL) is the apex laboratory for drug testing and its results are last and final. "The Hon'ble Allahabad High Court has held in the matter of Ramshankar Mishra Vs State of UP that under Section 25 (3) of the Drugs and Cosmetics Act, 1940 if the drug is found not of standard quality by the Govt. Analyst after test / analysis in the Govt. testing laboratory, the same is challengeable and the manufacturer has a right to adduce evidence in controversion of the report and can get the sample tested through court of law at the Central Drugs Laboratory, Kolkata for conclusive report. **However, if the drug is already tested in the CDL, then its report is conclusive and not challengeable"**. Copies of the letter intimating that the samples have been collected and sent for testing are at **Annexure IV.**

CDL conducted the tests of the samples and forwarded the test report stating that "The samples dose not conform to manufacturers specification with respect to Bacterial Endotoxin test." It is important to mention herein that all the four samples of Albupax manufactured by Natco Pharma Ltd. collected from different zones failed in Bacterial Endotoxin test. Copy of the CDL letter dated 13-7-2009 annexing test report is at **Annexure V.**

CDL also conducted test on the sample of Abraxene manufactured by Abraxis Bio-Science, USA and marketed by Biocon Ltd. Bangalore and forwarded the test report stating that "Sample conforms to manufacturers specification with respect to above tests only". Copy of the CDL letter dated 21/8/2009 annexing test report is at **Annexure VI.**

As all the samples of Albupax manufactured by Natco Pharma Ltd collected from various part of the Country were declared to be **"Not of Standard Quality"** and in view of the serious grave threat to the life of the cancer patients posed by the subject drug being **"Not of Standard Quality"**, it became incumbent upon the Licensing Authority [under Rule 21(b) that is DCG(I)] to take stringent action in the public interest under the provisions laid down in the D&C Act and Rules made there under after giving opportunities to the firm including show cause notice.

Rule 122 DB of the Drugs and Cosmetics Rule, 1945 reads as under

"122 DB- Suspension or Cancellation of permission/Approval – If the Importer or manufacturer under this part fails to comply with any of the conditions of the permission or approval, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons thereof, suspend or cancel it".

As the product of the Natco Pharma Ltd. Albupax had failed to conform to the conditions of Approval granted by the DCG(I) and in compliance with the aforesaid provision of Rule 122 DB as laid down under the Act, ***, show cause notice was issued to the firm giving an opportunity to explain why the Action should not be initiated against the firm under the provisions of Drugs & cosmetics Act & Rules made there under for manufacture & sale of drug declared to be " Not of Standard Quality" vide letter dated 16/7/09***. Copy of the letter dated 16/7/2009 is at **Annexure VII.**

For the defects of these nature Drugs Consultative Committee, a statutory body under the D&C Act had framed a detailed guidelines as **" Guidlelines for taking action on samples of Drugs declared spurious or Not of Standard Quality".** This Guideline which has been approved by the Ministry of Health and Family Welfare lays down the procedures to be followed while initiating prosecution. High level of endotoxin found in NATCO Pharma's product, comes under category B defect that is "Grossly Sub Standard Drug" which covers the defect of serious nature affecting the quality of the Drugs. Such defects arise out of gross negligence of Good Manufacturing Practices during the manufacture of the drug thus making the drug grossly Substandard. The Guidelines states a broad classification of cases where prosecution **should** be launched. Clause 4 of this part states that:-

"4. Where a parenteral preparation is reported by the Government Analyst to be non sterile, pyrogenic or toxic and provided on investigation is found to be sub-standard due to lack of adequate quality control and adherence to provisions of GMP in the manufacturing processes" .

As the Albupax, of Natco Pharma Ltd. is a parenteral preparation and had failed in the Bacterial Endotoxin test (Pyrogen), it came under the purview of aforesaid clause. As a result thereof the Licensing Authority had no option under the

Guidelines but to direct the investigation of the manufacturing site by the CDSCO, Sub-Zonal office, Hyderabad. Accordingly, a copy of Show Cause Notice dated 16/7/2009 was endorsed to ADC(I), CDSCO, Sub zone Andhra Pradesh under whose jurisdiction the manufacturers plant is located with an instruction to investigate the case & submit their report at the earliest. Copy of the letter to ADC (I) Sub-Zone Hyderabad dated 16/7/2009 is at **Annexure VIII.**

The investigation was conducted by the Drugs inspectors on 20/7/09 at the manufacturing premises of M/s. NATCO Pharma Ltd, Nagarjuna Sagar, Nalganda (dist), A.P. The report was forwarded by ADC (I), Hyderabad vide its letter dated 23/7/2009 to DCG (I). The investigation at the manufacturing site as conducted by the Drug Inspectors revealed various discrepancies of serious nature some of which are placed herein below:-

a) The kit used for BET test is M/s Lonza,USA with control standard endotoxin of E. coli and the sensitivity of lystate is 0.125 EU/ml. As per IP 2007 Appendix 2.2.3 page 26-31 it is indicated that the control standard endotoxin (CSE) used shall be suitably standardized against the Endotoxin Reference Standard (ERS) for Gel-Clot method maintained by CDL, Kolkata. However, the firm has not used the standardized CSE for BET test as per pharmacopoeia. The firm has validated the BET procedure by the LONZA LAL Test Kit only and not carried the validation studies with other Kits available in the market.

b) The vendor audit or evaluation for Human Albumin (20%) Indian Pharmacopeia was not carried out, though this is a critical raw material involved in the process wherein the test for Pyrogen need to be complied.

c) The TOC (Total Organic Carbon) levels of WFI (Water for Injection) were found to be raised during the period when the batches declared as not of standard quality were manufactured.

d) The facility inspection indicated that the filling and sealing equipment are manually operated though located in class B with mobile LAF (Laminar Air Flow) providing class A. The filling and sealing area has three doors with gaps, one for main entry, one for maintenance and the third for vial entry and the premises **do not comply the GMP norms.**

e) The environmental records for settle plate indicated that evaluation is not done at the vulnerable places for possible high microbial growth such as at the doors located in filling and sealing area.

The investigation team thus **remarked** that the manufacturing site has various irregularities and deficiencies of Schedule M (GMP), Schedule V (Standards of patent and proprietary medicines complying with the general requirements for injections as per IP with respect to Bacterial Endotoxin Test) and hence are in contravention to the provisions of the D & C Act & Rules. A copy of the letter dated 23/7/2009 containing investigation report is at **Annexure IX.**

ADC (I) Sub-Zonal office, Hyderabad in his above letter has also stated that the **manufacturer was given an opportunity** as per D & C Act to submit explanation within 28 days on the samples drawn by the Drugs inspector & declared as not standard quality. **The period of 28 days was given to the manufacturer as under the provisions of section 25 (3) the manufacturer could have adduced the evidence before the Inspector in controversion of the report. However, NATCO Pharma Limited did not avail the opportunity of challenging the test report under section 25 (3) of D & C Act.**

Section 25(3) of D&C Act is placed herein below:-

"25. Reports of Government Analysts.—

(1) .....

(2) .....

(3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence to the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken 5[or the person whose name, address and other particulars have been disclosed under section 18A] has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

(4) .....

(5).....

Natco Pharma Ltd. in their reply dated 12/8/2009 to the Drugs inspector, CDSCO, Sub-Zonal office, AP, referring to the investigation findings dated 20/7/2009, stated that earlier they were using Endosafe Kit (for WFI) and then switched over to Lonza kit. And further they also stated that they have been working on better

unambiguous method employing the latest sophisticated instrumental (chromogenic) **to circumvent reproducibility problem** and are in the process of revising & revalidating the Bacterial endotoxin test methods. A copy of the letter dated 12/8/2009 is at **Annexure X.**

In its response to the show cause notice issued by the DCG (I) on 16/7/09, M/s. NATCO Pharma Ltd. **vide its undated letter**, refuted / disputed the process of testing employed by CDL, Kolkata & further and stated that CDL, apparently did not use the kit (Lonza for gel clot method for Bacterial endotoxin test) provided by them which was completely false. A copy of the **undated letter** of Natco Pharma is at **Annexure XI.**

CDL, in its letter dated 13/7/09 has clearly stated that the samples were tested using both the kits. i.e. with lonza kit supplied by M/s NATCO Pharma as well as Charles River Endosafe kit. It has been further stated by CDL that Lonza kit supplied by the firm, did not respond to lysate even with positive control & no gel formation was observed, which indicate doubt about the quality and purity of the Lonza kit supplied by the firm. Hence, the contention of the NATCO Pharma that CDL apparently did not use the kit (Lonza for gel clot method for Bacterial endotoxin test) provided by them is completely false and erroneous.

It would further be observed from the investigation report that as per IP, Control Standard Endotoxin used shall be suitably standardized against the endotoxin reference standard for gel clot method, maintained by CDL, Kolkata. However the reference standard used by the firm was not as per IP requirement and hence, it was obvious that firm was using un-validated testing methodology therefore their averments about the process of testing by CDL was misconceived & unfounded.

Moreover the firm in their response to show cause notice has agreed that they have decided to control the endotoxin to a very low level and are revising process control which calls for revalidating all the system.

Surprisingly, the contention of the firm as expressed in their reply to Drug Inspector *with respect to circumventing the reproducibility problem of the endotoxin test method* was not averred categorically in their subsequent replies to show cause notice to DCG(I) & further appeal. It clearly shows that the firm had no clear cut, credible and cogent answers

to aver their contentions in an unambiguous and emphatic manner and they were only trying to avert the issue by employing different means as is apparent in their various replies.

Asst. Drugs Controller (I), Sub-Zone office, AP vide his letter dated 29-9-2009 stated that since the subject drug was drawn under the provision of D & C Act & Rules by drugs Inspector & samples were declared as not of standard quality failing in Bacterial endotoxin test and as provided under the Act, asked for necessary direction for further follow up steps under the provisions of D & C Act & Rules for administrative Action or prosecution.

It is pertinent here to mention that presence of high level of endotoxin in the injectable product may cause fever, chills, rigors & serious life threatening side effects including death. Above facts attain more gravity as Albupax (paclitaxal injection) is used in breast cancer patients, which is a Life threatening disease.

In this regard it is important to reiterate that

1.) The samples drawn (in Form 17) and forwarded (in Form 18) by Drug Inspector, CDSCO, Hyderabad were tested & reported (in Form 13) to be Not of Standard Quality by CDL, Kolkata (Appellate Laboratory) as per the provision of the Drugs & Cosmetic Act and rules.

2.) The firm had also not challenged or contravened the test report as per the provision 25 (3) of D & C Act, though the opportunity was provided to them.

3.) Also the investigation report conducted at the manufacturing site revealed serious lapses in the manufacturing and testing procedures followed by NATCO Pharma Ltd.

4.) The aforesaid violations by the firm are squarely covered under the guidelines for instituting prosecution as mentioned here in above. On the basis of the Investigation and the product being Not of Standard Quality, instructions/directions were sought from the DCG (I) to initiate prosecution under the Act against the NATCO Pharma Ltd.

5.) Moreover, failure of Albupax of Natco Pharma Ltd. to conform to the specification is also a violation of condition of Form 46 (marketing permission) granted by DCG (I).

In view of above facts and circumstances whereby all the samples, including statutory samples, of Albupax of NATCO Pharma Ltd. failed in Bacterial Endotoxin test in the Appellate Lab (CDL, Kolkata) and investigation has reported their gross non-compliance to GMP and testing requirements, posing a high health risk including death to the cancer patients, it became incumbent upon the DCG (I) under the Act as well as in

the public interest to allow the natural course of legal action including suspension / cancellation of permission and prosecution.

The suspension / cancellation of permission and prosecution are the natural corollary under the Act in situation where a product fails in the critical standards of quality threatening the lives of patients. In view of the firm's continuous failures on all fronts against various opportunities given to them, there was no situation or circumstance for not allowing the prosecution under the Act against NATCO Pharma Ltd.

Therefore, after giving various opportunities to the firm and investigating the matter for more than six months, on seeking legal opinion as part of due diligence, the permission of Albupax of NATCO Pharma Limited, (MF-873/08) for manufacture of new drug formulation was suspended vide letter dated 21/10/2009 and No Objection was granted vide letter dated 21/10/2009 for initiating prosecution under the Act against NATCO Pharma Ltd., Hyderabad. Copies of the letters are at Annexure XII.

(2.) Data on action taken by DCG (I) against such companies in last two or three years for the violation in similar cases in D&C Act:

In this regard it is mentioned that wherever the contraventions of provisions of Drugs and Cosmetic Act and Rules with respect to quality of the product were observed and reported, the prosecution or investigation or regulatory actions were recommended by DCG (I). The data in respect of such cases is given below:

1. Prosecution was recommended in 2008 against M/s Medi Pharma, Mumbai after the primary investigation of import of allegedly spurious drug (Vitamin B 12 from M/s Lervachem Co. Limited, Hongkong) under 9 (b) (e) of Drugs and Cosmetics Act and submission of forged documents to the authorities.
2. Complaint launched on 2nd Sep, 2009 against M/s J B Khokhani & Co. & M/s Sheetal Pharma Mumbai and M/s Envee Drugs Pvt. Limited, Nadiad, Gujarat including exporters, through Central Bureau of Investigation (CBI) which resulted in further launching of FIR and subsequent investigation for import of allegedly spurious drugs (Progesterone, Roxithromycin & Cimetidine from China) under 9 (b) (e) of Drugs and Cosmetics Act and submission of forged documents to the authorities.
3. Complaint launched in 2009 against M/s C J Shah & Co., Mumbai including exporters through Central Bureau of investigation (CBI) which resulted in further launching of FIR and subsequent investigation for import of allegedly spurious Ascorbic Acid (Vitamin C) under 9 (b) (e) of Drugs and Cosmetics Act and submission of forged documents to the authorities.

(127)

4. Complaint launched on 16.12.2009 against M/s Kawarlal & Co. & M/s Kawarlal & Sons, Chennai including exporters, through the Central Bureau of Investigation (CBI) which resulted in further launching of FIR and subsequent investigation for import of allegedly spurious drug (Tranexamic Acid from M/s Zhejiang Chemicals Import and Export Corporation, China) under 9 (b) (e) of Drugs and Cosmetics Act and submission of forged documents to the authorities.
5. Complaint launched on 16.12.2009 against M/s Adcock Ingrahm, Bangalore including exporters through the Central Bureau of Investigation (CBI) which resulted in further launching of FIR and subsequent investigation for import of allegedly spurious drug (Di-phenhydramine Hydrochloride from M/s Sino bright Development Limited, Wanchi China) under 9 (b) (e) of Drugs and Cosmetics Act and submission of forged documents to the authorities.
6. Complaint launched on 16.12.2009 against M/s Kawarlal & Co., Chennai including exporters through the Central Bureau of Investigation which resulted in further launching of FIR and subsequent investigation for import of allegedly spurious drug (Azithromycin from M/s Sunwell Chemical Co. Limited, China) under 9 (b) (e) of Drugs and Cosmetics Act and submission of forged documents to the authorities.
7. The Clinical Trial permission for Pneumococcal vaccine (13 valent) of M/s Wyeth Pharma Ltd., Mumbai was suspended under rules 122DB on 6-11-2008 due to report of death of an infant during the trial.
8. The Licences of CRI, Kasauli, BCG vaccine Lab Guindy, PII, Coonoor were suspended in January,2008 due to non-compliance to the conditions of the manufacturing Licence (Schedule M).
9. The DCG (I) asked State Licensing Authority of Delhi to suspend the Licence for manufacture and sale of J. Mitra & Co. Ltd., Delhi in 2008 on reported quality failures of its HIV diagnostic kit & contravention observed in the subsequent investigations in this issue.
10. The DCG (I) asked State Licensing Authority of Gujarat to suspend the Licence for manufacture and sale of M/s Span Diagnostics, Surat in 2007 on reported quality failures of its HIV diagnostic kit & contravention observed in the subsequent investigations in this issue.
11. Show cause Notice was issued to M/s GSK, Mumbai on 23-12-2009 due to contravention of Rule-106 of D&C Rules for advertisement of vaccination for prevention of Cervical Cancer.
12. The State Licensing Authority, Tamil Nadu was requested in Dec, 2009 to take urgent necessary action against granting license to manufacture Letrazole, 5mg tablet for

treatment of infertility which is considered as new drug, without approval from DCG (I) to M/s Burgeon Pharmaceuticals Pvt. Limited, Koil (TN) marketed by M/s Intas Pharma, Ahmedabad.

13. DCG (I) has written to State Drugs Controllers on various occasions to take necessary action against granting manufacturing license for various new fixed dose combinations (FDC's) which are considered as new drugs, without approval from DCG (I). Recently in Dec, 2009 in one such case, the State Licensing Authority, Puducherry was requested to take necessary action against grant of manufacturing license to manufacture FDC of Cefixime plus Ofloxacin Tablets without approval of DCG (I) to M/s Ascent Pharma Pvt. Limited, Puducherry marketed by M/s Piramal Health care.

Further DCG (I) has imposed the restriction / prohibition on certain cases of drugs because of safety concern and action taken by other regulatory authorities:

- All State Drugs Controllers were requested in 2006 to direct manufacturers to incorporate box warning in package inserts & promotional literature of Gatifloxacin regarding reported side effects of dys-glycemia associated with use of the drug.
- All State Drugs Controllers were requested in 2008 to direct manufacturers to incorporate box warning in package inserts & promotional literature of Rosiglitazone and Piolglitazone regarding reported side effects of Heart failure associated with use of these drugs.
- The permission to market new drug approval of Lumiracoxib granted to M/s Novartis was cancelled in 2008 because of safety concern and worldwide withdrawal of the drug.
- The importers / manufactures of new Drug, Rimonabant were asked to discontinue its manufacture / import of the drug in 2008 based on Safety concern and worldwide withdrawal of the drug.

The permissions for advertisement of Emergency Contraceptive Pills (Levonorgestral tablet) issued to M/s Cipla Ltd., Mumbai, M/s Incense Care, Bangalore and M/s PSI, New Delhi have been withdrawn on 11-1-2010 with immediate effect, as Gazette notification under section 15 of Drugs & Magic Remedies (Objectionable Advertisement) Act, 1945 exempting the application of the Act in relation to such advertisement of the drug has not been issued.

- The news item appeared in MINT on 26.3.2009 stating that permission to oral human insulin aerosol suspension was granted to M/s Shreya Life Sciences Pvt. Ltd. Mumbai, without Clinical Trial citing statement of Dr. M. Venketeshwarlu, the then DCG (I) that Phase III permission was granted by him. However, as per office record, instead of permission for Phase III, the import permission for marketing in India was granted by him with condition to conduct PMS studies to the parent company. In view of the reported contradictory statement associated with him on the clinical trial aspects and as the drug was only approved in Ecuador at that time, the import permission of said product granted to M/s Shreya Life Sciences Pvt. Limited Mumbai was withheld on 26/03/2009 for reviewing the matter.

3. Advise to conduct the testing of company's fresh products, after the stay order on suspension of license is implemented, at laboratory approved under D&C Act as recommended by Secretary (HR)

In this regard it is to mention that, the Statutory Sample under section 23 of the Act was collected for test / analysis of the impugned drug manufactured by the subject firm and was forwarded to the Central Drugs Laboratory, Kolkata under the Act. The Section 25 (4) is reproduced below:

(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the drug 3[or cosmetic] produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by, or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

As per the provisions of D&C Act Section 23 (3), the manufacturer as such has not notified in writing to the Inspector, within 28 days of the receipt of the copy of the report that he intends to adduce evidence in controversion of the report. It is important to mention here that Central Drugs Laboratory, Kolkatta (CDL) is the apex laboratory for drug testing and its results are last and final. The Hon'ble Allahabad High Court has held in the matter of Ramshankar Mishra Vs State of UP that under Section 25 (3) of the Drugs and Cosmetics Act, 1940 if the drug is found not of standard quality by the Govt. Analyst after test / analysis in the Govt. testing laboratory, the same is challengeable and the manufacturer has a right to adduce evidence in controversion of the report and can get the sample tested through court of law at the Central Drugs Laboratory, Kolkata for conclusive report.

(124)

However, if the drug is already tested in the CDL, then its report is conclusive and not challengeable.

In view of the same there is no provision under the Statute to get the statutory sample of already declared "Not of Standard Quality" drug by CDL, Kolkata retested.

However, since the stay order of the Central Government on suspension in subject case has already been implemented on 31.12.2009, as advised, the fresh samples of the Albupax as and when it is manufactured by M/s NATCO will be drawn and tested at a laboratory approved under Drugs and Cosmetic Act.

6/11/10

Mr. Rishikant Singh
Legal Advisor, CDSCO, (HQ)

6/11/10

Mr. Arvind Kukrety
ADC, CDSCO (HQ)

6/11/2010

Mr. A K Pradhan
ADC, CDSCO (HQ)

6/11/10

Dr. S E Reddy
ADC, CDSCO (HQ)

Lalit Kishore 6/11/10

Mr. Lalit Kishore
Advisor, CDSCO (HQ)

V.G.Som 6/11/2010

Dr. V. G. Somani,
DDC, CDSCO (HQ)
Chairperson

May like to see please

V.G.S. 6/11/2010 DDC(I)

DCG(I) Pls. up reply to the ministry pl.

12/11/10.

DDC(II)

V.G.S. 12/11/2010

ADC(AK)