MOST IMMEDIATE

X11035/1/2010-DFQC
Government of India
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi
Dated the 2 November, 2011

To

Drug Controller General (India)
FDA Bhawan, Kotla Road
Near Bal Bhawan
New Delhi

Subject: Suspension of permission/approval under Rule 122DB of Drugs and Cosmetics Rules, 1945 for the drug Albupax manufactured by M/s NATCO Pharma Ltd., Hyderabad, A.P.-regarding.

Sir,

I am directed to refer to your Note File No. QA/GNL/BCN/INV-ABR/09, dated 10th October, 2011 on the subject mentioned above and to say that ***suitable action may be taken in the matter as per the provisions of Drugs and Cosmetics Act and Rules.***

Yours faithfully

(Sudhir Kumar)
Under Secretary to the Government of India
Telefax: 23062292

File No. QA/GNL/BCN/INV-ABR/09

Directorate General of Health Services
Central Drugs Standard Control Organization
(O/o Drugs Controller General India)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: - 10/10/2011

It is to state that on 11th March 2009 complaints had been received from Biocon Ltd., Bangalore and Abraxix Bio- Sciences, USA, for taking action as Albupax manufactured by M/s. NATCO Pharma Ltd. Contains high level of toxic substances, (fails in Bacterial Endotoxin Test and Chloroform Level test). Acting on the complaint, on 2nd April 2009 Statutory Samples of Albupax was drawn by Drug Inspector Sub- Zonal office Hyderabad and sent for test to CDL, Kolkata. Subsequently on 9th April 2009 a Survey Sample of Albupax drawn by CDSCO, West Zone, Mumbai and sent for test to CDL, Kolkata. And on 15th April 2009 another Survey Samples of Albupax drawn and sent for test to CDL, Kolkata by CDSCO, North Zone office.

CDL, Kolkata forwarded test reports on 13th July 2009 declaring that these samples of Albupax are of, "Not of Standard Quality", as they do not confirm to manufacturers specifications with respect to Bacterial Endotoxin test. Accordingly a show cause notice was issued to M/s. NATCO Pharma on 16th July 2009 wherein they were directed to hold the manufacturing and sale of subject drug until further orders and also to recall these products from market under intimation to this office and they were also required to intimate why regulatory action like suspension or cancellation of permission bearing number MF-873/08 dated 18/08/2008 should not be initiated against them under the provisions of Drugs & Cosmetics Act and Rules for manufacture and sale of drug declared to be not of standard quality. Copy of letter was endorsed to ADC (I), CDSCO, Sub- Zone, Andhra Pradesh, with instruction to investigate the case and submit report.

In the meanwhile on 20th July 2009, investigation was conducted at M/s. NATCO Pharma which revealed various irregularities, deficiencies and contravention of Schedule M (GMPS) and Schedule V. ADC (I), CDSCO, Sub Zone, Andhra Pradesh, forwarded inspection report to office of DCG (I) on 23rd July 2009.

M/s. NATCO Pharma has submitted their reply for the show cause notice which was received by this office on 03/08/2009. In their reply they stated that they had suspended the manufacture and sale of the drug and recalled the stock from the market. Further they stated that CDL Kolkata did not follow proper test method and procedures.

Also in this matter, ADC (I), CDSCO, Sub Zone, Andhra Pradesh has requested to DCG(I) for directions for follow up action under the provisions of the Drug & Cosmetics Act on 29th September 2009, as the Statutory Sample drawn has been declared as, "Not of Standard Quality".

Legal opinion obtained from the legal consultant, wherein it was opined that new drug approval under rule 122 DB may be recalled with the respect to the subject drug and appropriate action should be initiated for manufacturing a "Not of Standard Quality" drug. In view their of keeping in mind the above mention facts in circumstances Permission / approval (MF-873/08) for manufacture of Albupax was withdrawn with immediate effect by DCG (I) vide F. No. QA/GNL/BCCN/INV-ABR/01, dated 21st October 2009.

Further ADC (I) sub zone, Andhra Pradesh was given NOC for taking appropriate action including initiating prosecution of M/s. NATCO Pharma for manufacturing not of standard quality drug under the provisions of Drugs and Cosmetics Act and Rules.

M/s. NATCO Pharma Ltd., in the meanwhile, made an appeal to the Secretary, Ministry of Health & Family Welfare for revocation of suspension order for the manufacture of albupax on 17th November 2009, and the Ministry of Health & Family Welfare stayed the operation of the order of DCG (I) dated 21.10.2009 with immediate effect pending a decision on the appeal filed by the company vide its order dated 23rd December 2009.

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The decision of the Central Government was conveyed to the ADC (I) sub zone, Andhra Pradesh, Director, Drugs Control Administration, Hyderabad and M/s. NATCO Pharma, Hyderabad on 31st December 2009.

It was also directed by Drugs Controller General (I), as required by Ministry of Health and Family Welfare vide letter F. No. QA/GNL/BCN/INV/ABR/09 dated 23-12-2009 in reference to the Stay Order in the above case, to draw fresh samples of Albupax Injectable Suspension Manufactured by M/s. NATCO Pharma Limited, Nagrjuna Sagar.

2567/US(D)/2011
12/10/2011

Subsequently the Central Government has allowed the appeal filed by the company, M/s. NATCO Pharma, Hyderabad by No.X.11035/1/2010-DFQC vide its order dated 12th August 2010 and cancelled the order of DCG (I) dated 21.10.2009.

Also the samples of fresh batches bearing Nos. 202678 & 202681 of "Albupax Injectable Suspension" which were drawn by the Sub-Zonal office A. P. Hyderabad was forwarded to Central Drugs Laboratory, Kolkata vide Form -18 No. 6-2(1)/ Zonal-AP/2010/674,675 dated 30-11-2010. The same were reported as Standard Quality and confirms to IP with respect to "Bacterial Endotoxins Test" vide CDL Test Report Nos. 32-10/2010-SS/DCA(S)-270/3059 & 271/3060 both dated 21-01-2011.

By letter dated 4th May 2011 Asst. Drugs Controller (I), CDSCO, Hyderabad, has forwarded this office the Legal advice of Additional Standing Govt. Council, Nalgonda Dist. A.P. who has opined as:-

"The material available creates benefit of doubt and may not sufficient to prove the allegations against M/s. NATCO Pharma Ltd. In a criminal prosecution the benefits of doubt always goes to the persons, whose against the accusation is made. As such in this case, the benefit of doubt goes to M/s. NATCO Pharma Ltd. In Spite of my opinion, if you want to file a complaint, please furnish the particulars of the constitution of the Firm and persons responsible for the manufacture of the subject drug".

No. 260/DCG(I)/11
13/10/11

In the matter it is stated that vide order dated 12th August 2010, the Central Government has allowed the appeal filed by M/s. NATCO Pharma and accordingly the order dated 21st October 2009 of withdrawal of permission/ approval for manufacture of Albupax as passed by DCG (I) was cancelled. Also the Additional Standing Govt. Council nominated at Nalgonda has opined that the material available creates benefit of doubt and may not be sufficient to prove allegations against M/s. NATCO Pharma Ltd.

In views of the aforesaid order dated 12th August 2010 as passed by the Central Government Order dated 12th August 2010 and the Additional Standing Government Counsel Legal opinion, as well as the fresh samples of the Firm has been declared as of standard quality it may not be feasible to file and prosecute M/s. NATCO Pharma before the court in absence of concurrent views.

However having said so, the facts are submitted to the Ministry for its considered opinion in this regard.

Controller General (India) DGHS
No. 507
12 OCT 2011
New Delhi

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