



INDIAN DRUG MANUFACTURERS' ASSOCIATION

102, POONAM CHAMBERS, 'A' WING, DR. A. B. ROAD, WORLI, MUMBAI 400 018, INDIA

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PARTNERS IN GLOBAL HEALTHCARE

9 April 2014

Dr. G. N. Singh,
Drugs Controller General (India),
Central Drugs Standard Control Organization,
FDA Bhavan, Kotla Road,
New Delhi 110 002.

Sub: Improper import of "Crude" Bulk Drug from China

Ref: Our letter dated 25 February 2014

*Received
15/4/14*

Dear Sir,

We had informed you vide our letter as above about "Crude" Theophylline being imported from China (copy enclosed). We had similarly informed the other concerned departments such as the Chief Commissioner of Customs, JNPT about this malpractice.

In response to our letter, we have received a reply [F.No. S/26-Misc-1342/2013-14 Gr. IIA-F dated --.03.2014] from Shri Ashish Mishra, Dy. Commissioner of Customs that the said goods have been imported by a 100% EOU unit under self assessment scheme and the goods have been released after getting an NOC from ADC (copy of the letter is attached).

We also refer to your circular dated 4th March 2014 informing all your officials at CDSCO and Ports that "only those drugs that comply with Drugs and Cosmetics Act & Rules should be allowed to be imported into India' (copy enclosed).

The letter from the Customs is forwarded to you for your information and necessary action as you deem fit.

Yours sincerely,

S V Veerramani
President

Encl: as above

CC: **Dr. V. G. Somani**, Joint Drugs Contrlller General (I), Central Drugs Standard Control Organization, FDA Bhavan, New Delhi.

AFFORDABLE MEDICINES FOR ALL



INDIAN DRUG MANUFACTURERS' ASSOCIATION

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25 February 2014

PARTNERS IN GLOBAL HEALTHCARE

Dr. G N Singh,
Drugs Controller General (India)
Central Drugs Standard Control Organization,
FDA Bhavan, Kotla Road,
New Delhi

Dear Sir,

Sub: Improper import of "Crude" Bulk Drug from China

We are informed by Members that "Crude" Theophylline has been imported in December 2013 from China as can be seen from the published Custom's Import Data for JNPT Port as under:

14- Dec- 13	29395900	CRUDE THEOPHYLLINE	JNPT	CHINA	N/A	12500.00	KGS	Sea
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You will appreciate that if such unauthorised imports continue, the domestic manufacturers of the Bulk Drug are put at a disadvantage, as also the importer gets monopolistic advantage over others who follow the rules. Importing "crude" form of a Bulk Drug can also be used to circumvent Registration requirements for Pharmaceutical products. The main purpose behind the need for Registration of the source is to safeguard health of the public, which will be jeopardised if such unauthorised imports are allowed. Even if the import is for export, then also the quality of the imported Bulk Drug cannot be guaranteed as the imported product being "crude" does not conform to any Pharmacopoeia.

We have had occasions in the past when we have had to draw the attention of the authorities to such unauthorised imports of bulk drugs as 'Crude'. We have pointed that in the past too that there is no such thing as a "crude" Bulk Drug as per CDSCO or under Drug Rules. It would amount to import of a "substandard" product. Thus, we would request you to investigate the matter further and take appropriate action to stop such imports which is detrimental to the domestic producers of the product as also the public health.

Yours Sincerely,

Daara B Patel
Secretary-General



AFFORDABLE MEDICINES FOR ALL

Faxed

1/4/14

**OFFICE OF THE COMMISSIONER OF CUSTOMS (EXPORT)
JAWAHARLAL NEHRU CUSTOM HOUSE, NHAVA SHEVA,
TAL URAN, DIST-RAIGAD, MAHARASHTRA - 400 707.**

F.No.S/26-Misc-1342/2013-14 Gr.IIA-F

Date: .03.2014

To

✓ Mr. Dagra B. Patel,
Secretary General,
Indian Drug Manufacturing Association,
102, Poonam Chambers, 'A' Wing,
Dr.A.B. Road, Worli,
Mumbai-400 008.

Mr. Jayan Magnumda
Mr. D. B. Mody
Mr. Mahesh Doshi
FYI Pl.
Rajiv
1/4/14

Gentleman,

Sub : Import of 'Crude Theophylline' by M/s. Bajaj Healthcare
Vide B/E No.4080799 dt. 14.12.2013 - reg.

Please refer to your office letter dated 25.02.2014 ref. No. Nil in connection with above subject.

The said goods have been imported by a 100% EOU unit under self assessment scheme. The goods have been released after getting an NOC from ADC.

Sivdhan
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On your part, you are also requested to sensitize your members to comply with the prescribed rules and regulations in the era of self assessment.

This issue with the approval of Commissioner of Customs (Export), JNCH.

Yours faithfully,

Ashish
12/5/14
(Ashish Mishra)

Dy. Commissioner of Customs
Gr.7U, JNCH

Cc Mr. S. V. K. S. Manan
Goyal




Central Drugs Standard Control Organisation
Office of Drugs Controller General India
FDA Bhawan, New Delhi-110002.

Dated: 4th March, 2014

NOTICE

The Central Drugs Standard Control Organization (CDSCO) is celebrating the year 2014 as "Patient & Animal Safety" year. In its endeavour to ensure the Mission of CDSCO "To safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices" in letter and spirit, it has been decided that the drug products which are being imported in the country be checked for their compliance with the provisions of the Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945. As the patient's safety is of paramount importance, it has been decided that the drugs for import into the country shall be allowed only if these are in compliance to the requirements of the Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945.


(Dr. G.N. Singh)
Drugs Controller General (India)

To

All Officers of CDSCO HQ/Zonal/Sub-Zonal Offices/Port Offices of CDSCO

Copy to: PS to DG/PS to AS&DG/PS to JS (R),
Ministry of Health & Family Welfare