



INDIAN DRUG MANUFACTURERS' ASSOCIATION

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

HAND DELIVERED ON 26/02/2014.
@ 2.30 PM.

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PARTNERS IN GLOBAL HEALTHCARE 25 February 2014

Dr. V G Somani,
Joint 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 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



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Drugs Controller General (India)
Central Drugs Standard Control Organization,
FDA Bhavan, Kotla Road,
New Delhi

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