PRESS NOTE NO.3

(1999 SERIES)

Government of India
Ministry of Industry
Department of Industrial Policy & Promotion
Udyog Bhawan,

SUBJECT: De-licensing of five bulk drugs.

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Modified policy for drugs and pharmaceutical industry (Drug Policy) inter-alia provides that industrial licensing for all bulk drugs and their formulations and for intermediates stands abolished except for the five bulk drugs (reserved for the Public Sector under the Drug Policy) and products produced by re-combinant DNA technology. This had been given wide publicity vide Press Note No.4(1994 Series) dated 25.10.94 issued by the Ministry of Industry. As an ongoing process of industrial reforms, Government have been considering for sometime the necessity of retaining the bulk drugs reserved for manufacture by the Public Sector under industrial licensing. The Government have recently decided to exempt the five bulk drugs from reservation for the Public Sector under the Drug Policy. The need for licensing these bulk drugs arose out of the need for reserving manufacture by the public sector. In the interest of the consuming public, therefore, it does not seem necessary to retain the five bulk drugs under licensing under the Industries (Development and Regulation) Act.

2. Accordingly, Government have decided to de-license the manufacture of the following five bulk drugs:

1. Vitamin B1
2. Vitamin B2
3. Tetracycline
4. Oxytetracycline
5. Folic Acid.

3. However bulk drugs produced by the use of re-combinant DNA technology and bulk drugs requiring in vivo use of nucleic acid as the active principles (items not classified under Harmonised System) and formulations based on use of specific cell or tissue targeted formulations (item not classified under Harmonised System) shall continue to remain under compulsory licensing.

4. The entrepreneurs who wish to avail themselves of the de-licensing of the five bulk drugs as at para 2 above would be required to file an Industrial Entrepreneurs' Memorandum (IEM) with the Secretariat for Industrial Assistance in the Ministry of Industry as laid down for all de-licensed industries in terms of the Press Note dated 2nd August, 1991, as amended from time to time.

5. Entrepreneurs who have been issued Letter(s) of Intent (LOI) for manufacture of any or all of the five bulk drugs (now de-licensed) need not file an initial IEM. In such cases the LOI holder shall only file Part "B" of the IEM at the time of commencement of commercial production against the LOI issued to them. It

is, however, open to entrepreneurs to file an initial IEM (in lieu of the LOI issued to them) if they so desire, whenever any variation from the conditions and parameters stipulated in the LOI/Industrial Licence is contemplated.

Sd/-

(ASHOK KUMAR)

Joint Secretary to the Government of India

New Delhi, the 26th February,1999.