

PART B

To be submitted at the time of Commencement of Commercial Production to the Secretariat for Industrial Approvals (SIA) Department of Industrial Policy and Promotion, Udyog Bhavan, New Delhi - 110 011 in 6 copies.

I Reference Number _____

II Actual Date of Commencement |__|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

III Actual Investment: (Amount in Rupees)

	Existing	Proposed
(a) Land (for rented Premises, Capitalised value of the same to be indicated)	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _
(b) Building	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _
(c) Plant & Machinery	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _
(i) Indigenous	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _
(ii) Imported	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _
(a) CIF Value	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _
(b) Landed Cost	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _
(iii) Total[(i)+(ii)(b)]	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _

IV. Item(s) of manufacture :In case of more than one item supplementary sheets may be attached.

*NIC No. |__|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

*ITC Code |__|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

Proposed Annual Capacity |__|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

Existing Capacity, (if applicable) |__|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

Total Capacity after Expansion |__|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

Unit of Capacity |__|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

V Employment	Proposed	Actual
(a) Supervisory	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _
(b) Non-Supervisory	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _	__ _ _ _ _ _ _ _ _ _ _ _ _ _ _

Place.....

Signature of Promoter(s)

.....

(Name in Block Letters)

.....

(Designation of the Promoter)

.....

|__|_|_|_|_|_|_|_|_|_|_|_|_|_|_|

Date Month Year

* To be filled wherever applicable

ANNEXURE

ADDENDUM TO MEMORANDUM TO BE FILED BY THE ENTREPRENEURS IN RESPECT OF PROPOSALS FOR DRUGS AND PHARMACEUTICALS COVERED UNDER NOTIFICATION REGARDING EXEMPTION FROM INDUSTRIAL APPROVALS

Information to be furnished for each item of manufacture separately:

A. PROPOSALS FOR BULK DRUGS/DRUG INTERMEDIATES/FORMULATIONS*

1. Name of the proposed item of Manufacture:
2. Approval under Drugs and cosmetics Act, 1940 and Rules made thereunder:
(Please indicate date and reference number of the approval, for use in the country, of the proposed Bulk Drug or of the Bulk Drug for which the proposed Drug Intermediates will be used, as the case may be, and enclose a copy thereof.)
3. Proposed Annual Capacity:
 - 1) Quantity (Unit):
 - 2) Ex-factory Value of Production (Rs. In Lakhs):
 - 3) CIF Value of :
 - (i) Imported raw materials required per kg of product (Rs.):
 - (ii) Product (if imported) (Rs. Per kg.):

4) Description of Proposed Process:
(Please furnish schematic diagram of chemical reaction sequences by giving chemical structures of reactants and products at each step.)

5) Source of technology:
(a) Developed through own R&D :
(Please give details of work done)

(b) Procured from indigenous sources(*):
(c) Involves foreign collaboration (*):
(* Please furnish name and address of the source and terms of payment.)

* (The name of the item of manufacture should comply with British Approved Name (BAN) ; United State Adopted Name (USAN) or International Non-Proprietary Names.)

6. Raw Material Requirement for the proposed Annual Capacity:

Sl. No.	Name of Raw Material	Unit	Quantity	Rs. In Lakhs	
				CIF Value If imported	Cost at Factory
(1)	(2)	(3)	(4)	(5)	(6)
		-	-	-	-

B. PROPOSALS FOR FORMULATIONS

Sl. No.	Name of the formulation and Dosage Form	Capacity	Composition Bulk ____ Drug Name ____ Strength	Total Qty. Kg/Lit.	Value Rs. In Lakhs	DCI/SDC Approval No. and Date
(1)	(2)	(3)	(4) _____ (5)	(6)	(7)	(8)
		-	-	-	-	

Note For Guidance of Entrepreneurs for Submitting IEMs

(This part contains information for guidance of entrepreneurs and may be retained by them, it need not accompany the application)

1. Under the notification No. 277 (E) dt.25.07.1991 Industrial undertakings have been exempted from the operation of sections 10,11,11A and 13 of the I (D&R) Act, 1951 subject to fulfillment of certain conditions. Section 10 refers to the requirement of licensing of new industrial undertakings. Section 11A deals with licenses for the production of new Articles. Section 13 refers, inter alia to the requirement of licensing for effecting substantial expansion.

Extracts from notification No. 477 (E) dated 25.07.1991.

Para 1 of Notification No. 477(E) dt. 25.7.1991 as amended from time to time

"EXEMPTION FROM INDUSTRIAL LICENSING

The Central Government hereby exempts from the operation of the provisions of Sections 10, 11, 11A, 13 of the I(D&R) Act, 1951, industrial undertakings exempted licensing are specified below:

A. (i) The article (S) of manufacture shall not be an article(s) included in schedule I, Schedule II or schedule II to the Notification and

(ii) The proposed project shall not be located within 25 kms from the periphery of standard urban area limits of cities having population of more than 10 lakhs according to the 1991 Census.

This condition shall not apply to:

(a) electronics, computer software, and printing industries and other non-polluting industries that may be notified from time to time.

(b) Other industries provided they are located with the industrial areas designated by the State Government(s) before 24.07.1991.

(c) The Small scale or ancillary industrials undertakings on their exceeding the investment limits prescribed for such industrial undertakings in the notification of government of India in the Ministry of Industry (Department of Industrial Development) No. 232 (E)dated 2.4.1991 (as amended by S.O. 857(E), dated 10.12.1997)

B. Section 11A of the said Act subject to the condition that the new article shall not be an article included in Schedule I, Schedule II, Schedule III to this notification and shall not involve any additional investment in plant and machinery.

III Industrial undertakings, other than the small scale and ancillary industrial undertakings covered by notification No. S.O 232(E), dated the 2.4.1991 (as amended by S.O. 857(E), dated 10.12.1997 availing of the exemption under Notification shall file with the

Department of Industrial Development (Secretariat for Industries Assistance), Memoranda as may be prescribed in this behalf by the Central government."

2. Subsequent to above Notification, video which only 18 industries were exempted from licensing, now only 9 industries remain under compulsory licensing for which IEM can not be filed.
3. In the case of proposals for drug and Pharmaceuticals the applicants should also fill up Annexure in prescribed Form. Part A is to be filled for Bulk Drugs/Intermediates and Part -B is to be filled for formulation. One IEM application should not contain more than 10 items of manufacture. Please read the Instructions carefully before filling the IEM application form.
4. Definition of a Small Industrial Undertaking (a) An industrial undertaking in which the investment in fixed assets in plant and machinery whether held on ownership terms or on lease or by hire-purchase does not exceed rupees three crore and equity holding by other industrial undertaking in it does not exceed 24 per cent of its total equity. The list of items reserved for exclusive production in the Small Scale Sector has been notified alongwith Gazette Notification No. 398(E) dated 3.4.1997.
5. Location While designated industrial estates located within 25 km of Standard Urban Area limit of 23 major cities are generally exempted from locational restriction for filling IEM, entrepreneurs should ensure that the industries proposed to be located in such designated industrial estates/areas are according a land use and zonal policies of the respective State governments.
6. Classification system Entrepreneurs may note that the description of article (s) to be manufactured should be stated according to the National industrial classification of all Economic Activity, (NIC - 19987).

Copies of the Notification Industrial Classification of all Economic Activity, 1987 can be obtained on payment from the controller of Publication, 1 Civil Lines, Delhi- 110054 or from any of the agents authorised to sell Government of India Publication. It has to be in conformity with the item(s) of manufacture.

7. General Instructions

- (a) For each item of manufacture, separate supplementary prescribed sheet, including Annexure for drugs and Pharmaceuticals) be added.
- (b) In a single IEM not more than 10 items be indicated. If IEMs is required for more than 10 items and additional fee of Rs 250 for each additional ten items should be paid.
- (c) Item(s) of manufacture falling under different Administrative Ministries require filing of separate IEM, alongwith a separate Demand Draft.
- (d) While submitting intimation of commencement of production return, (Form B) it may be ensured that NIC No. given in the return should be in conformity with the NIC No. Given in the IEM.
- (e) Separate applications may be filed for Ayurvedic (including Herbal preparations, Unani medicines and other related medicines) and Allopathic medicines.
- (f) It may be ensured that the IEM is complete in all respect.