

# Internal Guidelines No.-3/07/04/2008.

As per Para 8(1) of DPCO, 1995, the Government may from time to time fix the price of a scheduled formulation in accordance with the formula laid down in Para 7. Further, where the Govt. fixes or revises the price of any bulk drug under the provisions of this order and the manufacturer utilizes such bulk drug in its scheduled formulation he shall, within 30 days of such fixation or revision, make an application to the Govt. in Form-III for price revision of all such formulation and the Govt. may, if considered necessary, fix or revise the price of such formulations.

2. The Form-III lays down the specific details the companies are required to submit while making an application for approval or revision of prices of the scheduled formulations. A reference is invited to note-2 in Form-III of DPCO, relevant extracts of which are reproduced below:-

(a) A statement indicating the purchases made during the last three months with copies of invoices certified by Cost Accountant/Chartered Accountant shall be enclosed.

(b) Certified copies of recent batch production records or, in case production has not commenced, other documents maintained under Drugs and Cosmetics Act and the Rules made thereunder, in support of the quantities of raw materials claimed.

3. Further, as per Para 8(4) of DPCO, the Govt. is required to fix a revised price of such formulation or reject the application for revision for reasons to be recorded in writing, within a period of two months from the date of receipt of complete information.

4. It is clarified that in the absence of complete information regarding purchase of bulk drug and major raw materials during the last three months alongwith the copies of invoices certified by Cost Accountant/Chartered Accountant alongwith all other information required under the DPCO, 1995, the application submitted for revision of the price shall necessarily have to be considered as incomplete. NPPA shall have no option but to reject such incomplete applications in Form-III as not being in conformity with the relevant provisions of DPCO, 1995.