F. No. 19(78)/2014/Div.II/NPPA
Government of India
Ministry of Pharmaceuticals
National Pharmaceuticals Pricing Authority

YMCA Cultural Center Building
1, Jai Singh Road
New Delhi – 110001
Date: 03.03.2016

OFFICE MEMORANDUM

Subject: Revised checklist of documents to be attached along with Form- I application

As per the decision in the 26th Authority meeting (held on 24.02.2016) of NPPA, the following documents may be furnished by the manufacturer/marketing companies along with Form-I applications for price fixation of 'new drugs' under the Para 5 of DPCO, 2013:-

(i) Documents showing approval for the manufacture of new drug formulation granted by the Drugs Controller General of India (DCGI).

(ii) Documents showing the manufacturing permission granted by the State Drugs Control Authority for such new drug, in case of approvals before the cut-off date of 01.10.2012 and/or their renewals thereafter, if applicable, alongwith the documents showing submission of information to CDSCO regarding safety and efficacy of such FDC/ new drug formulation (as per DCG(I) order F. No. 4-01/2013/DC (Misc 13-PSC) dated 15.01.2013)*.

(iii) Documents in support of inclusion of such new drug formulation in Indian Pharmacopoeia (IP)/National Formulatory of India (NFI) till 07.11.2013 (as per amended Rule 122(E) clause (c) vide GSR 724(E) dated 07.11.2013 issued by Department of Health & Family Welfare).

(iv) Documents showing currently valid manufacturing permission by the State Drugs Control Authority.

(v) Copy of the agreement/contract entered into between the manufacturer and marketeer for new drug formulation.

(vi) Declaration by the company that the new drug formulation in question has not been prohibited by DCG(I), to be manufactured/marketed in India.

(vii) Any other document(s) considered necessary in support of the application.

2. This is in supersession of the earlier O.M. of even no. dated 24.7.2015.

(A.K. Khurana)
Director (Pricing)

*As per DCG (I) order F No. 4-01/2013/OC(Misc 13-Psc) dated 15.01.2013, *"in respect of other FDCs falling under definition of "New Drug" licensed by State Licensing Authority before 01.10.2012, without the permission of DCG(I), it has been decided that the DCG(I) will ask all the State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country.*

As regards new FDCs, if any, licensed by the State Licensing Authorities after 01.10.2012 without approval of DCG(I), the same will be considered for being prohibited for manufacturing and marketing in the country".