Policy Circular No. 19 /2009-2014 (RE 2010)

Dated: 14th February, 2011.

Subject: **Guidelines for availment of input combination for pharmaceutical products manufactured through Non Infringing (NI) process.**

Trade & Industry belonging to Pharmaceutical sector and the Pharmaceutical Export Promotion Council have been representing before Department of Commerce that neither the Standard Input Output Norm (SION) notified for the pharmaceutical products nor the adhoc norms ratified for such products by DGFT, allow them the actual requirement of inputs for manufacture of drugs (particularly the APIs) through Non Infringing (NI) process. Hence they have been requesting for inputs combinations based on actual consumption for such products.

2. The matter was deliberated upon in details in consultation with the stake holders. It has also been brought to notice that the product patent for a number of pharmaceutical products patented in the country of import, particularly in the developed markets, have expired or are in the verge of expiry. However the process patent still exists for such products. India has great potential to get a major share of production of such products adopting a different manufacturing process (without infringing upon the process patent) and export such products to those specific countries. During these discussions, it has been observed that the Standard Input Output Norm (SION) or the adhoc norm for an export product is based on the normal or standard route of manufacturing and the wastage norms are based on All Industry Average consumption data. Whereas manufacturing of a pharmaceutical product through NI process (wherein the product patent has expired but the process patent still exists in the country of import) entails higher wastage.

3. Foreign Trade Policy (FTP) provisions do not allow such dispensation. Once a SION has been notified for a product based on all Industry average or the adhoc norm for the product is ratified, inputs and the corresponding quantities are allowed as per SION or adhoc norms only and no additional quantity of input (irrespective of actual consumption) is allowed. Hence the manufacturer of pharmaceutical products through NI process, are not entitled for actual wastage than that of all Industry average of wastage norms (SION) or adhoc norm, irrespective of the country of export.

4. In view of above and various in-house deliberations, it has been decided to incorporate a new provision to allow this facility to pharmaceutical sector subject to fulfillment of certain specified condition and documentation thereof. Accordingly Notification No. 22 dated 14.02.2011 and Public Notice No.29 dated 14.02.2011 have been issued, detailing the new provision stated in paragraph 4.1.3 of FTP, paragraph 4.7A of the Handbook of Procedure, Volume 1, introduction of new application form viz. ANF 4J, Chartered Engineers certificate of input requirement in Appendix 32C and a new format in Appendix 23A along with a Central Excise certificate for actual consumption & amendment in guidelines for applicants in the application form (ANF 4F) related to redemption and Bond waiver.

5. These input combinations under NI process shall be country specific and exporter specific.

6. Trade & Industry is requested to see the details of the provision carefully in the aforesaid Notification and Public Notice on the subject. Any difficulty in implementation of the aforesaid guidelines shall be brought to the notice of this Directorate immediately.

This issues with the approval of DGFT.

Sd/-
(Tapan Mazumder)
Joint Director General of Foreign Trade