Public Notice No. 29/2009-2014 (RE- 2010)

Dated: 14th February, 2011

Subject:-**Incorporation of a new provision as paragraph 4.7A in the HBP. v1 to allow access to duty free inputs based on actuals, for pharmaceutical products manufactured through Non-Infringing process- regarding.**

I. Background for the amendment:

Advance authorisation scheme allows access to duty free inputs required to manufacture the export product. Inputs and its quantities are allowed either as per Standard Input Output Norms (SION) or adhoc norms, based on average consumption data of the relevant industry.

There are certain manufacturing processes covered under Process Patents. Therefore, benefit of SION or Adhoc norms for such products (which are still under Process Patent, but product patent of which has expired) cannot be availed by manufacturer, other than the Patent holder. Such manufacturer, who wish to manufacture and export the product through a Non-infringing (NI) Process may require inputs and input quantities, other than that prescribed as per existing norms (SION or adhoc norms). Hence it has been decided to:

a) Incorporate a new provision as paragraph 4.7A (as stated below) within the scope of advance authorisation scheme to allow this facility to pharmaceutical sector subject to fulfillment of certain specified conditions.
b) Prescribe a new Advance Authorisation Application Form as ANF 4 J for such products.
c)Specify a format of Chartered Engineer (Chemical) Certificate in Appendix 32 C. This certificate shall be based on verification and authentication of the input combination required for pharmaceutical products manufactured through NI process.
d) Incorporate a new format for the Consumption Details of the inputs used, to be verified and certified by the Jurisdictional Central Excise Official in Appendix 23A for these pharma products in lieu of Appendix 23 for other products.
e) Amend the Guidelines for applicants attached to the ANF 4 F (i.e. "Application Form for Redemption / No Bond Certificate against Advance Authorisation") to specify additional documents required for such pharmaceutical products.

II Accordingly, in exercise of the powers conferred under Paragraph 2.4 of the Foreign Trade Policy, 2009-14, the following amendments are being made in the Handbook of Procedures, Vol. 1, 2009-2014 (RE- 2010):

A new paragraph shall be added as **Paragraph 4.7A**, after the existing paragraph 4.7.6 of HBP, v1:

4.7A. Advance authorisation for Pharma products under Non-Infringing (NI) process.

Provision: RA may issue advance authorisation for pharmaceutical products manufactured through Non-Infringing (NI) process. A manufacturer exporter can avail the benefit of this provision even if the Standard Input Output Norm (SION) or the adhoc norm (under self declared basis in terms of paragraph 4.7 of the HBP, v1) for the said product is available. "Input combination permitted under NI process, as approved by the concerned agency of the regulated markets", shall be exporter specific and country specific and shall be available only when the exports are destined for the same country.

Application & Processing: An application for grant of an advance authorisation under this provision shall be made in ANF 4 J along with the documents prescribed therein, to RA concerned. Each and every application for advance authorisation in ANF 4 J shall be accompanied with the required documents stated therein.

Input combination permitted under NI process for manufacturing the product shall be certified by the Chartered Engineer (Chemical) in the format given in Appendix 32C, after due verification of the details of each input and its quantity as given in Abbreviated New Drug Application (ANDA) / Drug Master File (DMF) of the applicant. RA shall cross verify the requirement of inputs as per the Chartered Engineer certificate submitted along with the application to that shown in the application and issue the authorisation accordingly. RA shall not forward such application to NC and the inputs and export product so allowed by RA, shall be treated as input combinations permitted under NI Process.

Redemption of Authorisation: Provisions contained in paragraph 4.28 of HBP v1, 2009-14, except sub-paragraph (v), shall be applicable. RA shall compare the details of Appendix-23A, duly verified and certified by the jurisdictional Excise Authority, with that of the inputs made/allowed in the authorisation, before allowing

redemption or Bond-waiver against individual advance authorization issued for pharmaceutical product(s) manufactured through NI process. In this verification process, in case, it is found that the Authorisation holder has consumed lesser quantity of inputs than imported, Authorisation holder shall be liable to pay customs duty on unutilized imported material, alongwith interest thereon as notified, or effect additional export within the EO period. However, for the customs duty component, the authorisation holder has also the option to furnish valid duty credit scrips issued under Chapter 3 of FTP and DEPB.

Maintenance of Proper Accounts: Every advance authorisation holder shall maintain a true and proper account of consumption and utilization of duty free imported / domestically procured inputs against each authorisation as prescribed in Appendix 23A. This record in Appendix 23A format, duly verified and certified by the jurisdictional Excise Authority, shall be submitted to the concerned RA at the time of filing application for redemption / bond waiver. RA shall compare the details of Appendix-23A, with that of the inputs allowed in the authorisation, before allowing redemption or bond waiver against individual authorization. Such records shall be preserved for a period of at least three years from the date of redemption.

2. A new Aayaat Niryaat form namely, ANF 4J related to Application form for "Advance Authorisation / Advance Release Order (ARO) / Invalidation letter for Pharmaceutical Product, manufactured through Non-Infringing (NI) process" stands added, as appended to this Public Notice, as Annexure I.

3. A new Appendix, namely, Appendix 32C related to "Format of Chartered Engineer (Chemical) certificate for Pharmaceutical products manufactured through NI process" stands added, as appended to this Public Notice, as Annexure II.

4. A new Appendix i.e., Appendix 23A related to "consumption and stocks of duty free material allowed under Advance authorization for Pharmaceutical product manufactured through NI process" along with the Central Excise certificate on consumption introduced, as appended to this Public Notice, as Annexure III.

5. "Guidelines for applicants" in Aayaat Niryaat form (ANF 4F) related to "Application Form for Redemption / No Bond Certificate (Bond waiver certificate) against Advance Authorisation* stands replaced by the amended Guidelines as at Annexure IV appended to this Public Notice.

III. The effect of this Public Notice:

It has been stated in the "Background for the amendment" at Sl. No. I above.

Sd/-
(Anup K. Pujari)
Director General of Foreign Trade

(F. No. 01/94/180/AA/NI process/AM11/PC-4)

Annexure I
(Appended to Public Notice No. 29 dated 14.02. 2011)

ANF 4 J

For Advance Authorisation / Advance Release Order (ARO) / Invalidation letter for Pharmaceutical Product, manufactured through Non-Infringing (NI) process

[Please see paragraph 4.7A of HBP. v1 and the guidelines (given at the end of this ANF) before filling the application].

1. IEC Number

2. Applicant Details
i. Name
ii. Address

3. RCMC Details
i. RCMC Number
ii. Date of Issue
iii. Issuing Authority
iv. valid upto
v. Products for which registered

4. Industrial Registration Details
i. SSI / IEM / LOI or IL Registration Number
ii. Date of Issue
iii. Issuing Authority
iv. Products for which registered

5. Excise Details (For those registered with Central Excise Authority)
i. Excise Registration Number
ii. Issuing Authority

6. Status House Details:
i. EH / SEH / TH / STH / PTH

ii. Certificate Number
iii. Date of Issue
iv. Issuing Authority
v. Valid Upto

7. Application Fee Details
i Amount (Rs)
ii Demand Draft / Bank Receipt / Electronic Fund Transfer No
Iii Date of Issue
iv Name of the Bank on which drawn
v Bank Branch on which drawn

8. Total CIF value of Imports applied for
i. In Rupees
ii. In currency of imports
iii. In US $

9. Total FOB / FOR value of Exports to be made, excluding commission
i. In Rupees
ii. In currency of exports
iii. In US $

10. Value Addition (in %):

11. Port of Registration as per paragraph 4.19 of HBP v1 (for the purpose of imports):_____.

12. Country of Import (Destination Country):

13. Whether approval of the Food & Drug Administration / Concerned regulatory authority of the country of import received for the product: Yes / No.

14. Details of items to be exported / supplied under the Authorisation:

S No	Item Description	Item Technical Characteristics / Quality etc.	ITC (HS) Code	Quantity	Unit of Measurement	FOB / FOR Value (in Rs)	FOB / FOR value (in freely convertible currency)

15. SION or Adhoc Norms for the export product:

i. Whether SION fixed for the product: Yes / No
If yes, then state SION Sl. No.: _____.

ii. Whether Adhoc Norms fixed: Yes / No.
If yes, then state:
NC meeting No.: ____;
NC meeting date: _____;
Case No.: ____.

16. Details of items sought to be imported duty free under the Authorisation

S. No	Item Description	Item Technical Characteristics / Quality etc.	ITC (HS) Code	Quantity in metric units	CIF Value (in Rs)	CIF value (in freely convertible currency)	Total exemption from Customs duty

17. Details of other materials to be used in the export product and sought to be imported / procured from sources other than the Authorisation on which drawback benefits is to be availed (not to be filled if Drawback benefits are not being claimed):

Sl. No		**Imported Item**		**Indigenously Procured Item**	
Name, Technical Characteristics / Quality etc	Quantity in metric units	CIF Value	Name, Technical Characteristics / Quality etc	Quantity in metric units	Value

18. Details of Outstanding Export Obligation against Advance Authorisation(s) issued already:

S No	**Authorisation No**	**Authorisation Date**	**CIF Value (Rs)**	**FOB Value (Rs)**	**%age of EO fulfilled**		**Expiry Date of E period**
					Qty wise	Value wise	

19. Details of exports / deemed exports (including Intermediate supplies) made in the preceding 3 licensing years:

Licensing Year	**FOB Value of exports (in Rs Crore)**	**FOR Value of deemed supplies (in Rs Crore)**	**Total Export Performance (in Rs Crore)**

20. In case of request for issuance of ARO / Invalidation letter, please furnish:

i. Advance Authorisation No.:
ii. Date of Issue of Advance Authorisation:
iii. Name (s) of the Indigenous producer from where items are to be procured:
iv. Address (s) of the Indigenous producer from where items are to be procured:
v. Regional Authority of the Indigenous producer:
vi. Items to be supplied by the Indigenous producer: a. Description of individual items: b. Quantity of individual items to be procured: c. Value of individual items to be procured:

21. Address of the factory / premises where the items to be imported are proposed to be used:

22. Address of the jurisdictional Central Excise Authority under whose jurisdiction the factory / premises falls:

DECLARATION / UNDERTAKING

1. I / We hereby declare that the particulars and the statements made in this application are true and correct to the best of my / our knowledge and belief and nothing has been concealed or held there from. If found incorrect or false, it will render me / us liable for any penal action or other consequences as may be prescribed in law or otherwise warranted.

2. I / We undertake to abide by the provisions of FT(D&R) Act, the Rules and Orders framed there under, the FTP, HBP v1, HBP v2 and the ITC(HS) Classification of Export & Import Items.

3. I / We hereby certify that none of the Proprietor/ Partner(s) / Director(s) / Karta / Trustee of the firm / company, as the case may be, is / are a Proprietor / Partner(s) / Director(s) / Karta / Trustee in any other firm / Company which has come to the adverse notice of DGFT.

4. I / We hereby certify that the Proprietor / Partner(s)/Director(s) / Karta / Trustee, as the case may be, of the firm / company is/are not associated as Proprietor/Partner(s)/Director(s) / Karta / Trustee in any other firm / company which is in the caution list of RBI.

5. I / We hereby declare that I/we have perused the list of SCOMET items as contained in the Appendix 3 to the Schedule 2 of the ITC (HS) Classifications of Export-Import Items, 2004-09 and that the item(s) exported / proposed to be exported

does not fall within this list and that I/ We agree to abide by the provisions of the Policy for export of SCOMET items contained in the Foreign Trade Policy, Schedule 2 of ITC (HS) and the HBP v1, irrespective of the scheme under which the item is exported / proposed to be exported (the underlined portion will be deleted in case an application for export license for SCOMET item is being filed).

6. I / We hereby declare that no export proceeds are outstanding beyond the prescribed period as laid down by RBI or such extended period for which RBI permission has been obtained.

7. I hereby certify that I am authorised to verify and sign this declaration as per Paragraph 9.9 of the FTP.

Signature of the Applicant

Place
Date

Name
Designation
Official Address
Residential Address
Email:
Telephone No.(O):

GUIDELINES FOR APPLICANTS

(Please see paragraph 4.7 A of HBP v1)

A. For Advance Authorisation:

1. Two copies of the application must be submitted unless otherwise mentioned.
2. Each individual page of the application has to be signed by the applicant.
3. RCMC details need not be given if the same have already been updated in the IEC.
4. Bank Receipt (in duplicate) / Demand Draft / EFT details evidencing payment of application fee in terms of Appendix 21B.
5. In case of supplies to another advance Authorisation holder, original invalidation letter(s) shall be submitted. However, in case of switch over from physical exports / deemed exports to intermediate supplies, such invalidation letters can also be furnished at the time of redemption of advance authorisation.
6. Chartered Engineer (Chemical) certificate certifying the input requirements of raw materials in the format given in Appendix 32C.

7. A self certified copy of the approval letter for the product, from the Food & Drug Administration / Concerned regulatory authority of the country of import (Destination country).
8. In cases where import of fuel has been sought for under Advance Authorisation:
   a. Self certified copy of the permission issued to the manufacturer exporter by the competent authority (concerned State Electricity Board or Power Corporation or Regulatory Commission of the State) under Section 44 of the Electricity (Supply) Act, 1948 for the installation of captive power plant based on the specified fuel unless the permission is specifically waived by the State Electricity Board; and
   b. Self certified copy of the letter intimating the date of commissioning of the captive power plant from the concerned authority which issued the permission letter is to be submitted.

   Note: Import of only such fuel(s) shall be allowed which have / has been specified in the said permission.

B. For ARO / Invalidation letter:
Applicant may furnish information in respect of Sl. No. 1, 2 & 20 of the application only.

C. Please state 'Not Applicable' wherever the information / data is not applicable to you.

Annexure II

(Appended to Public Notice No. 29 dated 14.02. 2011)

APPENDIX 32 C

FORMAT OF CHARTERED ENGINEER (CHEMICAL) CERTIFICATE

(For Pharmaceutical Product manufactured through Non-Infringing process)

1. I am a Chartered Engineer (Chemical) with Registration No. _____ dated _____. This Certificate is being furnished as per the requirement of paragraph 4.7A of Handbook of Procedure, Vol. 1.

2. I hereby certify that the approval communication dated _____ of the Food & Drug Administration / concerned regulatory authority of the country of import _____(name of country) pertains to the Drug Master File (DMF) reference No._____, meant for the export product for which the advance authorisation application is being filed.

3. I have examined the details of requirements of inputs of the applicant M/s _____, _____(Name and address of the manufacturer exporter) with regard to their technical description / specification and the quantity against each input from the Abbreviated New Drug Application (ANDA) / Drug Master File (DMF) of the applicant, as given at Sl. No. 2 above and as approved by the Food & Drug Administration / Concerned regulatory authority of the country of import. I have also verified that the details of the export product and the inputs sought thereof in their application in 'Aayaat Niryaat Form (ANF 4 J)' are as per ANDA / DMF. I have also examined the proper norms of consumption and after technical scrutiny of relevant designs and drawings of the export product, I hereby certify that they are correct in all respects and are actually required for the execution of the export product, for which the application is made.

4. I hereby certify the export product and the requirement of inputs thereof as follows:

(a) Details of product(s) to be exported / supplied under the Authorisation:

Sl. No.	**Product Description**	**Technical Characteristics / Quality / Specification**	**ITC (HS) Code**	**Quantity (Along with the Unit of Measurement)**

(b) Details of inputs required as per ANDA / DMF of the applicant and that **as per SION or Adhoc Norms***:

Sl. No	**Input Description**	**Technical Characteristics / Quality / Specification of the Inputs**	**ITC (HS) Code**	**Quantity (Along with the Unit of Measurement)**	**Quantity allowed as per SION or Adhoc Norms***

* State "NIL" in case the SION or the adhoc norm for the said export product is not available.

5. I am issuing this certificate having verified the approval of the concerned department / authority of the regulated overseas market and the details of each input and its quantity as given in ANDA / DMF of the applicant to that declared in the Aayaat Niryaat Form (ANF 4 J) and found them to be correct.

6. In the event that any of the statements / facts certified above by the undersigned, is found to be incorrect, I am liable for penal action under the Foreign Trade (Development & Regulation) Act, 1992 (as amended), Rules and Orders framed there under and the provisions of any other Act, in force.

Date: Signature of Chartered Engineer
(Chemical)
Place: Name:
Seal of Chartered Engineer: E-mail:
Tel. No. (O):
Official Address:
Residential Address:
Registration Number:
Name & Address of the Institution with which registered:

Note :

1. Unless and otherwise provided for, solvent(s) shall be allowed maximum upto 25% of the requirement of solvents indicated in the ANDA / DMF for the purpose of advance authorisation. However, in cases where recovery is not possible and the solvent gets poisoned, full quantity of solvent as per ANDA / DMF shall be allowed. Chartered Engineer shall verify and certify the same accordingly for the details of solvents required as in Table 4(b) above.
2. In case of deemed exports, this certificate shall be based on details given in ANDA of the recipient unit and DMF of supplying unit (deemed exporter).

Annexure III

(Appended to Public Notice No. 29 dated 14.02. 2011)

APPENDIX 23 A

Format for accounting of consumption and stocks of duty free imported or domestically procured raw materials, components etc. allowed under advance authorisation for pharmaceutical product manufactured through Non Infringing (NI) process (Please read paragraphs 4.7A, 4.28, 4.30 of the HBP. v1)

Inputs allowed in the authorisation	Product(s) exported under the authorisation	Balance	In case of balance inputs as in column 9	Remarks

Sl No.	Authorisation No (s) with date	Name of the Inputs	Quantity	Name of the Product	Quantity	Inputs Actually consumed for the exported product**		inputs, if any (4 - 8)	Additional exports effected in proportion to excess inputs	Input quantity reduced proportionate-ly in the authorisation*	Customs duty paid alongwith interest	
						Inputs	Quantity (Including actual wastage incurred)					
1	2	3	4	5	6	7	8	9	10	11	12	13

*Applicable only in case either partial import or "NIL" import has been effected.

** In case of post export replenishment, details of inputs used (whether duty paid or not) in the exported product has to be furnished.

We declare that the aforesaid particulars are correct.

Signature of the authorisation holder

Place:

Name in block letters:

_____.

Date:

Full official address:

_____

Full Residential address: _____

Official Seal / Stamp

Telephone No.:

_____

E-mail:

_____

Note:

1. Please mention N.A. wherever the information required in the table is not applicable.
2. For columns 10 & 12 of the table, please furnish the copy of the documentary evidence.

FORMAT OF CENTRAL EXCISE CERTIFICATE

I hereby confirm that I have examined the production details and the records of M/s _____(Name of the authorisation holder) and verified the details furnished in Appendix 23A format. I hereby certify the following details of consumption of inputs for the pharmaceutical product, manufactured through Non Infringing (NI) process, against their advance authorization No. ---------- dated ----------.

1. Name of the Advance Authorisation holder:
2. Address of the manufacturing unit:
3. Name of the exported product:
4. Type of exports: Physical / Deemed / Both (pl strike out whichever is not applicable).
5. Period for which production details verified:
6. Quantity exported against the authorization:
7. Details of inputs consumed in per unit of exported product:

Sl. No.	Name of the Input(s) used	Quantity consumed
1		
2		

Date:
official:
Place:
Office seal/Stamp:

Name of the Central Excise

Designation:
Telephone No. (O):
E-mail address (if any):
Postal Address:

Note:

1. This certificate shall be required only when the product manufactured and exported is a pharmaceutical product manufactured through Non-Infringing (NI) process. This certificate is to be signed by an official not below the rank of Superintendent of Central Excise, under whose jurisdiction the manufacturing unit of the Advance Authorisation holder is located).

2. As per the policy provision, solvent(s) shall be allowed maximum upto 25% of the requirement of solvents indicated in the ANDA / DMF. However, in cases where recovery is not possible and the solvent gets poisoned, full quantity of solvent as per ANDA / DMF shall be allowed. Central Excise Authority shall verify and certify the actual requirement of solvents accordingly for the purpose of Sl. No. 7 above.

Annexure IV

(Appended to Public Notice No. 29 dated 14.02.2011)

GUIDELINES FOR APPLICANTS

[Please see paragraphs 4.7 A, 4.25 & 4.26 of HBP v1]

1. Two copies of the application must be submitted unless otherwise mentioned.
2. Each individual page of the application has to be signed by the applicant.
3. FOB value of export for the purpose of V.A shall be arrived at after excluding the Agency Commission, if any. This provision shall be applicable for authorizations issued on or after 1.4.2008.

4. Application must be accompanied by documents as per details given below:

   (1) For physical exports:

   I. Bank Certificate of Exports and Realisation in the form given at Appendix 22A or Foreign Inward Remittance Certificate (FIRC) in the case of direct negotiation of documents or Appendix 22D in case of offsetting of export proceeds. However, realisation of export proceeds shall not be insisted if the shipments are made against confirmed irrevocable letter of credit or bill of exchange is unconditionally Avalised/ Co- Accepted/ Guaranteed by a bank and the same is confirmed by the exporters bank and certified by the bank in column 14/15 of Appendix 22A. For status holders, irrevocable letter of credit would suffice.

   II. EP copy of the shipping bill(s) containing details of shipment effected or bill of export in case of export to SEZ.

   III. A statement of exports giving details of shipping bill wise exports, indicating shipping bill number, date, FOB value as per shipping bill and description of export product.

   IV. A statement of imports indicating bill of entry wise item of imports, quantity of imports and its CIF value.

   V. In case where CENVAT credit facility on inputs have been availed for the exported goods, the goods imported against Advance Authorisation shall be utilized only in the manufacture of dutiable goods whether within the same

factory or outside (by a supporting manufacturer) even after completion of export obligation, for which the authorisation holder shall produce a certificate from either the jurisdictional Central Excise Supdt. Or Independent Chartered Accountant, at the option of the exporter.

VI. In case of a pharmaceutical product manufactured through Non Infringing (NI) process, duly filled in Appendix 23A duly verified and certified by the jurisdictional Central Excise Authority on consumption of inputs against the advance authorisation.

(2) <u>For deemed exports</u>:

I. A copy of the invoice or a statement of invoices duly signed by the unit receiving the material and their jurisdictional excise authorities certifying the item of supply, its quantity, value and date of such supply. However in case of supply of items which are non excisable or supply of excisable items to a unit producing non excisable product(s), a project authority certificate (PAC) certifying quantity, value and date of supply would be acceptable in lieu of excise certification. However, in respect of supplies to EOU/EHTP/ STP/ BTP, a copy of CT-3/ARE-3 duly signed by the jurisdictional excise authorities certifying the item of supply, its quantity, value and date of such supply can be furnished in lieu of the excise attested invoice (s) or statement of invoices as given above.

However in case of supply of the product by the Intermediate supplier to the port directly for export by the ultimate exporter (holder of Advance Authorisation or DFIA) in terms of paragraph 4.13 of HBP v1, copy of the shipping bill with the name of domestic supplier as Intermediate supplier endorsed on it along with the file No. / Authorisation No. of the ultimate exporter and the intermediate supplier shall be required to be furnished.

II. Payment certificate from the project authority in the form given in Appendix-22C. In the case of Advance Authorisation for Intermediate Supplies/ deemed exports, supplies to the EOUs / EHTPs / STPs/ BTPs, documentary evidence from the bank substantiating the realisation of proceeds from the Authorisation holder or EOUs / EHTPs / STPs / BTPs, as the case may be, through the normal banking channel, shall be furnished in the form given at Appendix 22B. However realisation of proceeds shall not be insisted upon if the shipments are made against confirmed irrevocable inland letter of credit or inland bill of exchange is unconditionally Avalised / Co-Accepted/ Guaranteed by a bank and the same is confirmed by the exporters bank and certified by the bank in column 5/6/7 of Appendix 22B. For status holders, irrevocable inland letter of credit would suffice.

III. A statement of supplies giving details of supply invoices and indicating the invoice number, date, FOR value as per invoices and description of product.

IV. A statement of imports indicating bill of entry wise item of imports, quantity of imports and its CIF value.

V. In case where CENVAT credit facility on inputs have been availed for the exported goods, the goods imported against Advance Authorisation shall be utilized only in the manufacture of dutiable goods whether within the same factory or outside (by a supporting manufacturer) even after completion of export obligation, for which the authorisation holder shall produce a certificate from either the jurisdictional Central Excise Supdt. Or Independent Chartered Accountant, at the option of the exporter.

VI. In case of a pharmaceutical product manufactured through Non Infringing (NI) process, duly filled in Appendix 23A duly verified and certified by the jurisdictional Central Excise Authority on consumption of inputs against the advance authorisation.