

INSPECTION REQUEST FOR API MANUFACTURING SITE LOCATED IN EXTRA-EU COUNTRY

To: AIFA

Ufficio Ispezioni e Autorizzazioni

GMP Materie Prime

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Subject: Inspection request for APIs manufacturing site (name and address)

I _____, born in

_____, on _____, in accordance with articles 46 and 47 of d.p.r. 28.12.2000, n. 445,

HEREBY DECLARE

- Of being the Legal Representative/ delegate¹ of _____ which manufacturing site is in (full address) _____, tel. n. _____, fax _____, legal headquarters in _____ (full address) _____;
- Of being aware that false acts and declarations are punishable by law and that, if such declaration is in fact found to be false, the declarer will no longer have any benefits consequent to the false declaration act, as prescribed by articles 75 and 76 of said act;
- that the documents contained on CD/USB Drive, originally formed on analog support, comply with the originals documents according to d.lgs. n. 82/2005 (Digital Administration Code) and the d.p.r. of 28 december 2000 n. 445.

HEREBY ASK

A GMP inspection for the APIs manufacturing site (name and address)

Information on the site and the APIs imported to Italy:

- Name, address and contact details of Italian customers
- Name, address of extra-EU manufacturing site

¹Improper entry be deleted; in case of delegate a statutory declaration in accordance with artt. 38-47 of d.p.r. n. 445/2000 to be attached

- Contact details of Quality Unit Responsible of the API extra-EU manufacturing site
- Names of the APIs requested to be inspected
- Date of the Italian submission of MA dossier

In accordance to article 38, comma 3, of d.p.r. 28.12.2000, n. 445, a photocopy of the identification document is attached to the present document.

Place and date _____

In witness

(signature and stamp)