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

To: AIFA

Ufficio Ispezioni e autorizzazioni
GMP materie prime
PEC: gmpapirequest@aifa.gov.it

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/ delegate[1] 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.

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
- Contact details of Quality Unit Responsible of the API extra-EU manufacturing site

[1]*Improper 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*

- Names of the APIs requested to be inspected
- Date of the Italian submission of MA dossier

In accordance to article 38, comma 3, of DPR 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)