ANSM - French National Agency of Medicine and Health Products Safety

Form for receipt of the fee following the performance of a requested inspection

ANSM DI - INSMP (234) 143/147, bd Anatole France 93285 Saint-Denis cedex

France

Contact

Articles L.5321-3 and D.5321-7 of the Public Health Code stipulate the payment of a fee to be received by the government, to benefit the Employees National Health Plan (Caisse nationale de l'assurance maladie des travailleurs salariés) whenever the ANSM conducts an inspection at the express request of an establishment engaged in the activities mentioned in Article L.5138-4 of said code (www.legifrance.gouv.fr). The amount of the fee is determined based on the above-mentioned articles. Signature of the present document signifies acceptance of payment of the fee, which will be paid to the Public Treasury upon receipt of the respective invoice.

Article D.5321-7 of the French Public Health Code, Decree n°2012-1016 of September 3rd, 2012 - Art. 1 (for information purpose only):

[...] 2. Pursuant to Point 2 of Section I:

"For the performance of an inspection expressly requested by an establishment carrying out the activities mentioned in Article L.5138-4 in order to verify observance of the best practices mentioned on Article L.5138-3, and to issue, as appropriate, the certificate confirming such observance, the amount of the fee is comprised of a fixed portion of 1,000 euros and a variable portion calculated based on each day of inspection started at the site and limited to 9,000 euros, according to the following scale:

"- If the establishment inspected is located in a country that is a member of the European Community or in a country that is a party to the European Economic Area Treaty: €300 per day;

"- If the establishment inspected is located in any	other country: €3,000 per day. []
Name of the establishment inspected	
Complete address of the establishment inspected (including the country)	
Establishment located in the EEC or part of the treaty on the European economic area	☐ Yes ☐ No
Address for invoicing (if different)	
Name of the contact at the establishment inspected Function Telephone Fax E-mail address	
Start date and time of the inspection End date and time of the inspection	
Number of days to be invoiced Inspection fee	
Name and signature of the inspector in charge, certifying the dates and start/end times of the inspection [Place], [date]	
Name and Signature of the entitled person	
(Stamp of the establishment)	