ANNEX 1

JUSTIFICATION REPORT TEMPLATE FOR LIST EXPANSION

Doctor

XXXXXXXX

Director General of the General Office of Research and Technology Transfer (OGITT)
National Institute of Health

To my highest consideration:

I am pleased to address you and forward to your office a request for an extension to the List of Products and Supplies. The reason for this request is: (please specify why and for what purpose the product is needed. If this is an increase from the initially approved quantity, it is essential to include calculations for the estimated import requirements.)

- **ÿ Mention the effective date of the insurance policy.**
- **ÿ If the list extension is due to an amendment to the informed consent or research protocol, the date of authorization of said amendment will be indicated.**

Finally, the following documents are attached:

- **ÿ FOR-OGITT-033 clean version. ÿ FOR-OGITT-033 change control version (modified items must be underlined and with a different color or highlighted).**

ANNEX 2

MODEL OF JUSTIFICATION REPORT FOR MODIFICATION OF THE LIST

Doctor

XXXXXXXX

Director General of the General Office of Research and Technology Transfer (OGITT)
National Institute of Health

To my highest consideration:

I am pleased to address you and forward to your office a request to modify the List of Products and Supplies. The reason for this request is: (please specify the reason and purpose of the modification).

- **ÿ Mention the effective date of the insurance policy.**

Finally, we attach the following documents:

- **ÿ FOR-OGITT-033 clean version ÿ FOR-OGITT-033 change control version (modified items must be underlined and with a different color or highlighted).**
- **ÿ If the batch number is modified, the batch number release analysis certificate and the labeling project must be attached. If the manufacturer or country of origin is modified, the Good Manufacturing Practices certificate must also be attached.**