Attestation regarding Addition of a New Manufacturer/Distributor Name Resulting from a Private Label Agreement (Manufacturer Attestation)

State of ____________  SS
County of ___________

I, ____________________, being duly sworn, state the following:

I am the ________________ (title) of ___________________ (company name) and I am authorized by ___________________ (company name), to make this statement.

In our request for an addition of a new manufacturer/distributor name for the following product(s) listed on DMECS (attach current DMECS product(s) listing) (hereafter referred to as “Product(s)”), I attest that the following is true:

(1) that ____________________ (manufacturer company name) (hereafter referred to as “Manufacturer”) and ______________ (distributor company name) (hereafter referred to as “Distributor”) have entered into a Private Label Agreement under which Manufacturer will manufacture the Product(s) for sale by Distributor to the exact specifications, without modification, as set forth in the most recently approved HCPCS coding verification application for the Product(s), except that labeling may be changed to reflect Distributor’s name and related information;

(2) that Distributor will make no alterations to the Product(s), except for the aforementioned labeling changes to with regard to Distributor’s name and information; and
(3) that no Product has changed in any respect from the most recently approved HCPCS coding verification application for that Product and/or the Product will continue to meet applicable FDA labeling requirements, and subsequently, if there are any changes made to a Product and/or if a Product fails to meet applicable FDA labeling requirements, a new HCPCS coding verification application will be submitted to the PDAC for coding verification.

______________________________
(signature)

______________________________
(name)

______________________________
(title)

On this ___day of __________, 20___, before me, a notary public, personally appeared _______________ who upon being duly sworn, acknowledged to me that he/she is the person described above, and who acknowledged to me his/her execution of the foregoing instrument.

______________________________
Notary Public

My Commission Expires:__________