



QUALITY ASSURANCE RENEWAL CHECKLIST

The items on this checklist identify issues that the PMRA has noted as frequently requiring clarification during the processing of the renewal application. Ensuring that these items are verified by applicants prior to submitting the renewal application will minimize the requirement for clarifications and assist in timely product renewal.

On the *Application for Registration Renewal Form* have you:

- Indicated whether the product is marketed or not?
- Ensured that addressing information is current and complete?
Where changes have occurred that have not yet been conveyed to the PMRA, ensure that you have included a notification letter. (Please refer to DIR2001-04)
- Identified the currently registered container type and size?

With respect to Labels have you:

- Included an electronic copy of the most recently approved bilingual label text (separate English and French text files) in PDF normal (portable document format), and included two (2) hard copies of the marketplace label if the product is marketed?

With respect to Renewal Fees have you:

- Included a completed Fee Form, and enclosed the appropriate fee (\$154 per product)?

On the *Statement of Product Specification Form (SPSF)* have you:

- For the SPSF for a Technical Grade Active Ingredient (TGAI) ensured that the name and address in Box H reflects the manufacturing plant address (i.e., physical site location where the active is produced) and for Manufacturing Concentrates (MA) and End-Use Products (EP) ensured that the name and address in Box H reflects the formulating plant (i.e., physical site location where the MA or EP product is formulated)?
- Verified the % purity, the Registration Number and whether the guarantee is a minimum or nominal for the active components (e.g., technical active ingredient, manufacturing concentrate) that is currently used to formulate this product?
- Verified the identity of formulants that are currently used to formulate this product including their CAS and list numbers? Where proprietary mixtures are used in the formulation, indicate the word *mixture* in place of the CAS numbers? (Box 7)
- Verified that the % w/w for each product component is correct and that the total of all the components adds up to 100%? (Box 9)
- Indicated the certified limits and verified that they have been calculated correctly? (Boxes 11,13) (Please refer to Regulatory Directive DIR98-03)
- Verified that the guarantee has been expressed correctly? (Box 14)

For Technical Grade Active Ingredient products being renewed have you:

- Ensured that the *Technical Grade Active Ingredient (TGAI) Site of Manufacture Information - Renewal* form 6116 has been completed?

Have you also:

- Informed the registrants of private label product(s) associated with your initial product(s) that you have renewed or discontinued their affiliated registrations(s)?
- Retained a copy of the *Application for Registration Renewal* form(s) for your own records and sent the original copy to the address below?

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Thank you for your assistance!