Health Canada Santé Canada

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Notice

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Integrated Review Process (Pre-Evaluation) and Screening

The Therapeutic Products Directorate (TPD) announces updated screening criteria for generic pharmaceutical pre-market submissions to replace the Integrated Review Process (pre-evaluation). TPD has made significant changes within the organisation to increase generic review performance capacity so that our review resources are focused in a manner which will enable us to reduce and eliminate the current backlog of generic drug submissions while at the same time minimise financial penalties. By eliminating the Integrated Review Process (IRP) for generic drugs and replacing it with the screening process, this will ensure that review resources are focused on the review of complete submissions.

The updated screening criteria for Abbreviated New Drug Submissions (ANDS) and their supplements (SANDS) will help assess the completeness of the drug submission and identify significant deficiencies prior to the review process. A key component to the screening of the ANDS will include an attestation checklist to assist sponsors in ensuring that the submission filed is complete and that key required information in support of the submission is provided in the filing. Generic manufacturers will be expected to include a completed attestation form in their submission to indicate that this required information has been provided. This attestation will be assessed as part of the screening process. Sponsors are asked to include the completed attestation form in **both PDF and Word format** in their ANDS or supplement in **section 1.2.3.** Failure to provide a completed attestation form will result in the issuance of a Screening Deficiency Notice.

Drug Master File (DMF) Process Changes

In the Integrated Review Process, significant deficiencies noted during pre-evaluation of the "Closed" portion of DMFs were forwarded directly to the DMF Holder. In the updated screening process, sponsors will confirm through the attestation form if DMFs and requisite Letters of Authorization have been provided. Should the DMF not be in order (fees paid, accessible), a Screening Deficiency Notice (SDN) will be issued. The "Closed" portion of the DMFs will no longer be verified at screening.

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Screening Process

The screening process remains unchanged and will continue to be carried out in accordance with the Guidance for Industry: *Management of Drug Submissions* (MDSG). Significant deficiencies noted during screening will be forwarded to the sponsor in either a request for clarification or a Screening Deficiency Notice (SDN).

Once acceptable responses to the requested information have been received from the sponsor, the submission will be accepted for review. If the sponsor fails to provide all requested information, the submission may be rejected in accordance with the Management of Drug Submissions Guidance.

Implementation

The implementation of these updated screening criteria and the attestation form will start with all new ANDS and supplements received by the Office of Submissions and Intellectual Property as of February 1, 2013. However, the attestation form will be accepted for submissions filed from January 2, 2013 onwards.

Questions should be directed to:

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