Refuse to File (RTF) Mechanism

Formulated October 26, 2016

I. In order to improve submission quality, the Food and Drug Administration (the "FDA") has promoted the Refuse to File (RTF) Mechanism.

II. Principles for RTF:

(1) Failure to enclose "complete administrative data" according to the Guidelines for the Registration of Medicinal Products.

(2) Failure to enclose "complete technical data" according to the Common Technical Documents (CTDs) format.

(3) Failure to pay the review service charge according to the Guidelines for Review Charges for Inspection and Registration of Western Medicine and Medical Devices.

III. Time for RTF:

(1) When any material is missing from a submission, then within 60 days of submission for registration, the FDA will unilaterally refuse to file via an official letter.

(2) If no RTF notice has been received, this means that the application has entered the subsequent review process.

IV. The applicant may resubmit the application within four months following the RTF by enclosing all required materials; such re-submission, however, may only occur once.

V. This mechanism is applicable to all applications for registration of new drugs submitted from January 1, 2017 onward.