An application submitted by a manufacturer to the Food and Drug Administration (FDA) for approval to market a new drug (a new, non-biological molecular entity) for human use.

Other definition: A file that is submitted to the competent authorities by a manufacturer to obtain a notice of compliance for a new drug and that contains phases I, II and III clinical trials.

Note: The term *new drug submission* is used in Canada and the term *new drug application* is used in the United States.