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explain the basis for important or unusual aspects of the prescribing information. The Clinical Overview should generally be a relatively short document (about 30 pages). The length, however, will depend on the complexity of the application. The use of graphs and concise tables in the

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these findings together with any other relevant information (e.g., pertinent animal data or product quality issues that may have clinical implications). The Clinical Overview is primarily intended for use by regulatory agencies in the review of the clinical section of a marketing application. It should also be a useful reference to the