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Comment from Kermit Kubitz

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General Comment

Because the renewal of PDUFA legislation has required FDA to utilize a structured Benefit Risk assessment, as a means of identifying and weighing both risk factors and health contributions, NDA submissions should have and include a preliminary structured Benefit Risk table, While the actual benefit risk may be revised and determined by agency action a structured benefit risk assessment by applicants, with a corresponding acceptance or if necessary revision by the FDA would meet the PDUFA commitments already made by the FDA, would provide guidance to applicants, and would, on approval or disapproval, inform the medica and patient community of the value of new drugs both in terms of their effects on the disease or symptom to be treated as well as other possible impacts on the patient's health. This would increase informed consent to drug use as well as allowing patient communities to analyze the reasons for use or non use or approval or disapproval of regulated drugs

The FDa already has a format for the structured Benefit Risk assessment, including condition, other alternatives, benefits and efficacy, risks and counter-indications, and a summary SBR conclusion. Having drug applicants submit preliminary versions would aid agency decision making and patient understanding

At present there is no collated file of SBR tables for recent drug actions. FDA should have a link to tables of Structured Benefit Risk results, given the agency's PDUFA commitments.