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**Paperwork Reduction Act Statement:** The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete the Ratings Worksheet (the time estimated to read, review, and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).