

Premarket Industry Perception Survey (Final- 2011)

Please offer your level of agreement with each of the following statements. Your options are, strongly disagree, disagree, agree, strongly agree and not applicable.

1. CDRH reviewed and processed your premarket submission in a timely manner.

1	2	3	4	5
Strongly Disagree	Disagree	Agree	Strongly Agree	N/A

2. CDRH staff treated you in a fair, courteous, and professional manner.

1	2	3	4	5
Strongly Disagree	Disagree	Agree	Strongly Agree	N/A

3. CDRH review staff exhibited a level of scientific expertise appropriate to review your submission.

1	2	3	4	5
Strongly Disagree	Disagree	Agree	Strongly Agree	N/A

4. CDRH review staff applied consistent review procedures in processing your submission.

1	2	3	4	5
Strongly Disagree	Disagree	Agree	Strongly Agree	N/A

5. CDRH website information and guidance documents provided adequate direction on the format and recommended contents of your submission.

1	2	3	4	5
Strongly Disagree	Disagree	Agree	Strongly Agree	N/A

6. CDRH guidelines, standards, and policies are adequate to prepare your submissions on the latest advancements in technologies.

1	2	3	4	5
Strongly Disagree	Disagree	Agree	Strongly Agree	N/A

7. CDRH staff used an interactive review process.

1	2			
Yes	No			

8. If yes to Question # 7: CDRH interactive review process is helpful to you.

1	2	3	4	5
Strongly Disagree	Disagree	Agree	Strongly Agree	N/A

9. CDRH premarket review meetings have been productive and have met your needs.

1	2	3	4	5
Strongly Disagree	Disagree	Agree	Strongly Agree	N/A

10. You have successfully submitted an eCopy premarket application through CDRH.

1	2	3	4	5
Strongly Disagree	Disagree	Agree	Strongly Agree	N/A

11. Whether the final decision was positive or negative, CDRH tried to be helpful throughout the review process.

1	2	3	4	5
Strongly Disagree	Disagree	Agree	Strongly Agree	N/A

12. What suggestions would you offer to increase the CDRH Reviewer's ability to appropriately review premarket submissions?

13. What suggestions would you offer to improve CDRH's education of the medical device industry?

14. What suggestions would you offer to improve the CDRH website?

15. Do you have any further comments or suggestions on CDRH's premarket review process?