U.S. Food and Drug Administration
Office of Regulatory Affairs
Foreign Medical Device and Radiological Health Inspections
10903 New Hampshire Avenue
Silver Spring, MD 20993
Telephone: (301) 594-4715
www.fda.gov

Contact Information for Foreign Medical Device Inspections

Optional Method for FDA 483 Responses

In addition to submitting a physical FDA-483 response via standard mailing methods, the U.S. Food and Drug Administration (USFDA), Center for Devices and Radiological Health's (CDRH) Office of Product Evaluation and Quality (OPEQ) are offering foreign establishments another method for submission of your timely response to the FDA-483. This method is entirely voluntary and can be used instead of sending your response by regular mail or express courier.

How do I submit my FDA-483 Response following my inspection?

Electronic Submission Method: The Office of Product Evaluation and Quality within the Center for Devices and Radiological Health has created an electronic mail account that is dedicated to the receipt of foreign establishment responses to the FDA-483. We will consider the scanned copy of the letter and any attachments to be your **official** response. Please send responses to: cdrhforeigninspections@fda.hhs.gov.

What information do I need to include in my 483 Response?

Please include the following with your electronic response:

a) A scanned copy of the original signed response letter in Portable Document Format (PDF).

b) Scanned copies in PDF form of any documentation that explains the corrective actions that have been or will be taken to bring your firm into full compliance. Please provide a translation of any documentation that is not in English to facilitate our review.

c) The **Subject** line of the message should include the firm's name, FEI number and FDA-483 response date. For example, "Subject: Firm name, FEI#: 0003330044, FDA-483 response dated XX/XX/20XX".

d) A maximum of ten (10) PDF files can be submitted electronically. Each PDF file should be uniquely numbered, e.g. 1FDA-483 response, 2Documents, 3Documents, 4Documents, and 5Documents. Alternatively, in the body of the email, please indicate that a series of emails will be sent and identify the attachments that will be included in each email. Please note that file names containing special characters, i.e. @, #, %, etc, cannot be processed by FDA. File names should exclude use of any special characters.

e) The maximum size of the entire electronic response cannot exceed 100 MB. Anything larger will be rejected by the FDA e-mail system. If your response exceeds 100 MB, then please consider zipping/compressing the files or consider sending multiple emails.

If you choose this optional method, then **DO NOT** submit a duplicate hard-copy response. Your electronic response is sufficient and is considered your firm's official response.

Please remember that CDRH's normal business hours are in the Eastern Standard or Eastern Daylight Savings Time Zone.

You will receive a follow-up e-mail message acknowledging receipt of your electronic response.

If we have trouble opening your message or any of the attachments, then we will request that you submit a paper-copy of the document(s).

Who can I contact if I have any questions?

Contact the following email address(es) with questions:
cdrhforeigninspections@fda.hhs.gov

Following review of the inspection, CDRH may issue a copy of the EIR and the FMD-145 letter if the inspection was determined to be acceptable.

More Information

For general medical device regulatory questions, you may contact the Center for Devices and Radiological Health's (CDRH) Division of Industry and Consumer Education (DICE).

E-mail: DICE@fda.hhs.gov
Phone: 1(800) 638-2041 or (301) 796-7100
www.fda.gov/DICE

- **For training videos and slides, visit:**
  www.fda.gov/Training/CDRHLearn
- **For general information about device registration and listing, visit:**
  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/
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  www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/
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