U.S. Food and Drug Administration
Office of Regulatory Affairs
Office of Medical Device and Radiological Health Operations (OMDRHO) Division 1 – East
One Montvale Avenue
Stoneham, MA 02180
Telephone: (781) 587-7500
www.fda.gov

New FDA Contact Information

July 20, 2017

Your firm now has new FDA contacts to correspond with regarding your medical device inspections. Your inspections are now managed by the Office of Regulatory Affairs' Office of Medical Device and Radiological Health Operations (OMDRHO) Division 1 – East.

What is the Office of Medical Device and Radiological Health Operations (OMDRHO) Division 1 – East?

This Program Division solely works with medical devices. It covers the states of: CT, DE, IN, KY, MA, ME, MD, MI, NH, NJ, NY, OH, PA, RI, VA, VT, WV and the District of Columbia.

Who do I contact following my FDA inspection?

E-mail your inspection-related correspondence to the email address listed below. A copy will be sent to the home District where your firm is located. Thumb drive or compact disc (cd) may be sent to the address below.

√ **E-mail correspondence to** oradevices1firmresponse@fda.hhs.gov

U.S. Food and Drug Administration
Office of Medical Device and Radiological Health Operations Division 1 – East
ATTN: OMDRHO Div1 Correspondence
One Montvale Avenue
Stoneham, MA 02180

Who do I contact about my medical device recall?

Contact e-mail address oradevices1recalls@fda.hhs.gov

How do I submit my correspondence?

OMDRHO Division 1 – East prefers e-mail correspondence due to efficiency, fiscal responsibility, expedited service to stakeholders and environmental awareness. The Division will acknowledge receipt of e-mail (size limit 100 megabytes) sent to oradevices1firmresponse@fda.hhs.gov

Please be sure that any attachments are readily labeled and/or identified for ease of review. Documentation should be submitted as a single pdf file, with bookmarks to easily identify table of contents, memos, attachments, etc. If a single pdf file exceeds the 100MB size limit, please submit multiple pdf files, with bookmarks, as appropriate. Please do not provide multiple folders that contain individual files as this will delay the processing of your response. There is no need to provide a back-up hard copy of any correspondence sent via email or provided in thumb drive or cd format.

Please contact the FDA Administrative Officer either via phone at (781) 587- 7451 or email at donna.dismukes@fda.hhs.gov if any questions.

What other contact information do I need to know?

The Program Division Director (PDD), OMDRHO Division 1 – East manages all inspections and compliance activities. Joseph Matrisciano, DD/PDD may be reached at joseph.matrisciano@fda.hhs.gov

The Director of Compliance Branch (DCB), OMDRHO Division 1 – East manages FDA-483 responses and post-inspection compliance activities and can be reached at oradevices1actingdcb@fda.hhs.gov

The Director of Investigations Branch (DIB), OMDRHO Division 1 – East, manages all inspectional activities. Arduino Frankovic, DIB, may be reached at arduino.frankovic@fda.hhs.gov

The Supervisory Administrative Management Specialist (SAMS), OMDRHO Division 1 – East manages administrative activities. Donna Dismukes, SAMS, may be reached at donna.dismukes@fda.hhs.gov

Why are you changing my FDA contacts?

In May 2017, as part of a broader agency initiative called program alignment, the U.S. Food and Drug Administration's (FDA) Office of Regulatory Affairs (ORA) implemented a program-based management structure that aligns staff by FDA-regulated product. This organizational approach replaces a management structure based on geographic regions. The changes within ORA are being made as part of the agency's Program Alignment strategy to modernize and strengthen the FDA's workforce and improve our public health response.

For more information on program alignment, visit:
https://www.fda.gov/aboutfda/centersoffices/officeofglobalregulatoryoperationsandpolicy/ora/ucm549087.htm

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 Assistance (DICE)

E-mail: DICE@fda.hhs.gov
Phone: 1(800) 638-2041 or (301) 796-7100
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactDivisionofIndustryandConsumerEducation/default.htm

- **For training videos and slides, visit:**
  https://www.fda.gov/Training/CDRHLearn/

- **For general information about device registration and listing, visit:**
  https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm

- **For general information on recalls, corrections and removals, visit:**
  https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm

- **For general information on mandatory reporting requirements, visit:**
  https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/