NIH CAP's "An FDA Afternoon" Webinar March 31, 2020 @ 2:00pm EDT

The National Institutes of Health (NIH) Commercialization Accelerator Program (CAP) [NIH CAP], Larta Institute, and the Food & Drug Administration (FDA) are pleased to present "An FDA Afternoon" online webinar. This event is for HHS/NIH SBIR/STTR small businesses and others interested in learning more about how businesses can communicate and interact with the FDA and access FDA resources, as well as information and insights for what to consider when communicating with the FDA. REGISTRATION REQUIRED.

DAY: March 31, 2020 (Tuesday)
TIME: 2:00pm to 5:00pm (EDT)
LOCATION: WEBINAR/ONLINE ONLY (Registration Required)

ADVANCE REGISTRATION REQUIRED (LINK): Register at this link https://attendee.gotowebinar.com/register/1610760750309501699 prior to the Webinar (webinar availability will be on a first-come, first-serve basis)
AGENDA:

SESSION 1:

- **Speaker: F. Ray Ford, Jr**, Pharmacist, CAPT, USPHS, CDER/OCOMM/DDI/SBIA.
  Ray is a Consumer Safety Officer in the Office of Communication's Division of Drug Information and has been with the FDA since 2011. Prior to joining the FDA, he served in the Indian Health Service as a Clinical Pharmacist and Safety Officer for the Fort Yuma Service Unit. He graduated from the Medical University of South Carolina in 1999, and 2001.

- **Content: CDER 101 – This session will provide attendees with a basic understanding of how to effectively communicate with FDA.**

SESSION 2:

- **Speaker: Danielle Fau**, M.S.E.
  Danielle Fau, M.S.E., is a Biomedical Engineer and on assignment to the Innovation Team the Office of Strategic Partnerships and Technology Innovation (OST), in the Center for Devices and Radiological Health (CDRH)/FDA. In this role, Ms. Fau works to address patient access barriers to medical devices. Prior to joining OST, Ms. Fau was a Biomedical Engineer and Lead Reviewer of Gastroenterology and Endoscopy products in the Office of Product Evaluation and Quality (OPEQ). Before commencing her career in the federal government, Ms. Fau worked for five years domestically and internationally in the Medical Device Industry, as a New Product Development Engineer and Whitaker International Fellow. Ms. Fau received

her Masters and Bachelors of Science in Engineering, majoring in Materials Science and Engineering, from the University of Pennsylvania.

- **Content: CDRH 101 - This session will provide important insights for accessing resources from CDRH, interacting with CDRH review teams, staying current on special programs, and considering market access earlier in the device lifecycle.**

SESSION 3:

- **Speaker: Rochelle Fink**
  Rochelle is a Senior Health Science Specialist at FDA. She is an experienced food and drug, healthcare, and intellectual property attorney. She serves as liaison between FDA and the Centers for Medicare & Medicaid Services (CMS under the U.S. Department of Health and Human Services (HHS)).

- **Content: This session will provide an overview of CMS – coverage, reimbursement; coding and what you need to consider to successfully approaching CMS.**

If you have any questions or require anything further, please do not hesitate to contact Larta at jcorrea@larta.org.

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