FDA Research Opportunities in the Office of Antimicrobial Products

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Background

- In 2011, FDA developed a strategic plan for regulatory science

FDA's core responsibility is to protect consumers by applying the best possible science to its regulatory activities — from pre-market review of efficacy and safety to post-market product surveillance to review of product quality

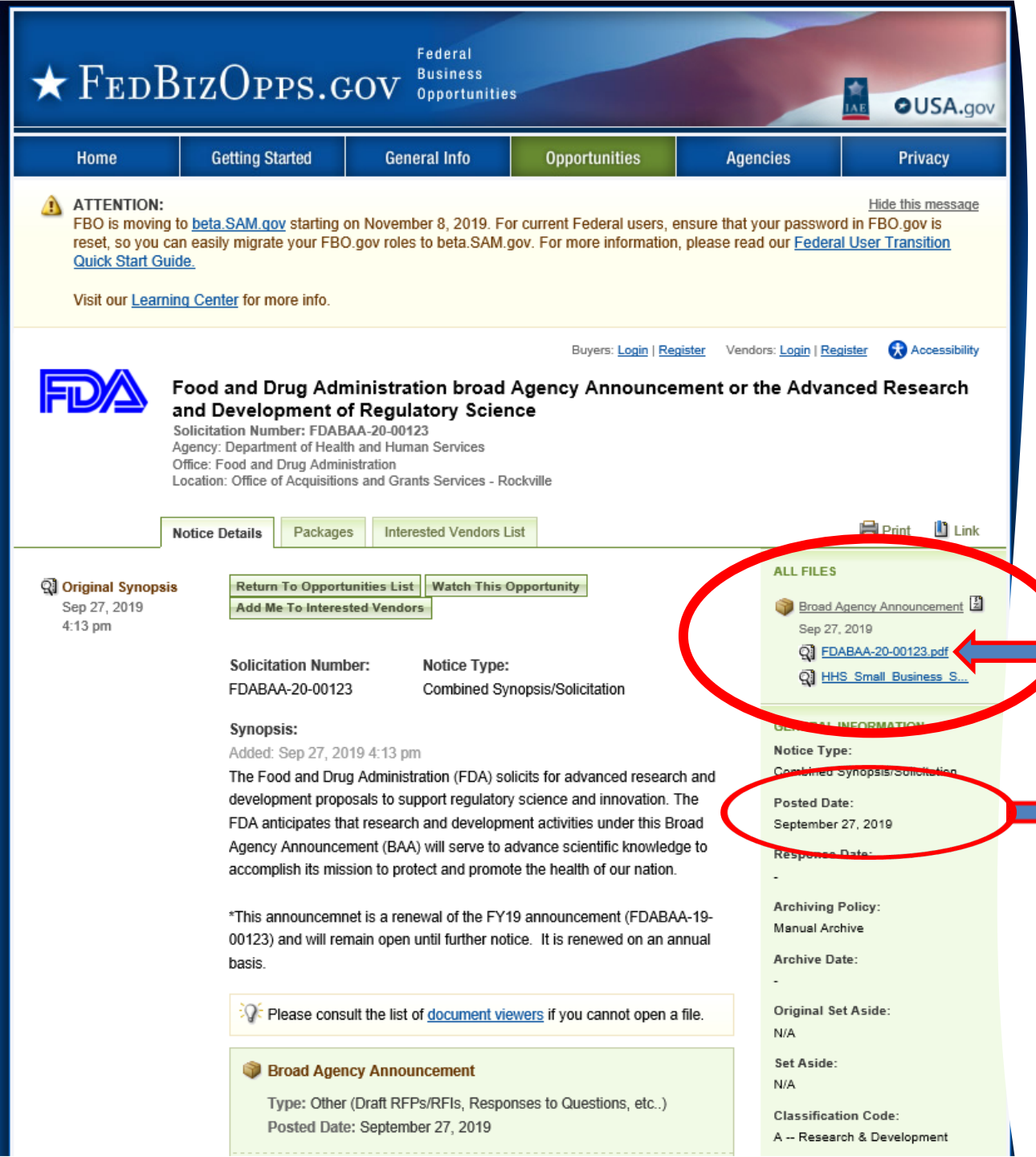
https://www.fda.gov/science-research/advancing-regulatory-science/strategic-plan-regulatory-science

Broad Agency Announcement (BAA)

- **Purpose**
  - Solicitation for research and development to support regulatory science and innovation

- FDA has an ongoing BAA

  https://www.fbo.gov/index?s=opportunity&mode=form&id=2313b4c8ab7a967d880cf16dee4ec116&tab=core&_cview=0



- Document outlines Research Areas of Interest
- Directions for Proposal Preparation and Submission

GENERAL INFORMATION

Notice Type:

Combined Synopsis/Solicitation

Posted Date:

September 27, 2019

New DAVP Research Opportunity

- Purpose:
  - To address gaps in our current knowledge regarding diagnosis, management, and outcomes of adenovirus infection in pediatric hematopoietic stem cell transplant (HSCT) recipients
- Goal:
  - To apply the knowledge gained from the research to inform drug development of novel antiviral products to treat adenoviral infections

Solicitation Number: FDABAA-20-00123; research area 5.2.12 (page 22)

BAA Listing for Adenovirus Project: 5.2.12

Use real-world data to characterize the natural history and current management of adenovirus (AdV) infections among pediatric hematopoietic stem cell transplant (HSCT) recipients.

Pediatric HSCT recipients are vulnerable to potentially life-threatening opportunistic infections, including AdV infections. At present, there are no FDA approved treatments for AdV infections, making this an area of unmet medical need. Research in this area is made challenging by the heterogeneity in approaches to diagnosis and management of AdV infection in HSCT patients. FDA seeks to better understand the breadth of practices and how these different approaches affect outcomes. The results of the proposed study may inform clinical trial design (including endpoint development) and help foster drug development for AdV infections. The work could involve collecting and analyzing data from multiple major transplant centers in the United States to address knowledge gaps around epidemiology/burden of disease (e.g. rates of infection and types of illness caused by AdV), monitoring and diagnosis (e.g. monitoring protocols, assay types), management (e.g. threshold for starting treatment and treatment modalities) and outcomes and factors affecting outcomes (e.g. host factors, transplant characteristics, and concomitant medications).

A multi-center, non-interventional, retrospective study is preferred to address these research questions. In addition to serving as a study site, potential offerors will manage operational aspects of the study (e.g. serve as a Data Operations Center for all study sites), including collaboration with FDA.

BAA Application Process

- Stage 1: Quad Chart/White paper submission by March 13, 2020
  - FDA will review the submission on technical merit and contribution to FDA's mission
  - FDA's OAGS will send a letter to offerors to submit full proposals
- Stage 2: Full proposals submission by early Summer (by invitation)
  - FDA Technical Evaluation Process
- Funding to be awarded through a BAA procurement contract
- Initiate research study by September 30, 2020

Interested? Please Apply!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