

Overview of the Division of Viral Products

January 14, 2016 VRBPAC

Discussion of the June 17, 2015
Site Visit for the Laboratory of
Method Development

Jerry P. Weir, Ph.D., Director
Division of Viral Products/OVRR/CBER/FDA

Division of Viral Products

Office of Vaccines Research and Review



Division of Viral Products

Mission and Functions

- Regulate viral vaccines and related biological products, ensuring their safety and efficacy for human use
- Facilitate the development, evaluation, and licensure of new viral vaccines that positively impact the public health

Division of Viral Products

Major Responsibilities

- Investigational New Drug (IND) and Biologics License Application (BLA) review, and other pre-marketing activities (e.g., pre-IND)
- BLA supplement review, lot release review, and other post-marketing activities (e.g., Biological product deviations)
- Manufacturer inspections (pre- and post-licensure)
- Consultation with other public health agencies (e.g., WHO, CDC, NIBSC)
- Conduct research related to the development, manufacturing, evaluation, and testing of viral vaccines

The Role of Research in the Division of Viral Products

- Research and laboratory activities complement the regulatory mission
- Address issues related to regulated viral vaccines
- Anticipate and address issues related to the development and evaluation of new viral vaccine products
 - General issues applicable to many products or product classes (e.g., cell substrate issues, improved test methods, etc.)
 - Specific product issues (correlates of protection necessary for efficacy evaluation, animal models necessary for animal rule implementation, etc.)

Division of Viral Products Staff & Budget Overview

- Division Staff – FY15
 - 77 FTEs
 - ~ 40-50 contractors (ORISE)
 - Postdoctoral fellows
 - Postbac students
 - Supported by targeted funds/external grants & contracts
- Division Budget – FY15
 - Standard operating budget ~ \$4,277,000
 - Targeted CBER support ~ \$1,992,000
 - Pandemic Influenza, Modernizing Science & Critical Path
 - Medical Countermeasures ~ \$903,000
 - External DVP funds ~ \$1,663,000

Division of Viral Products Staff (FTEs) - by Laboratory

- DVP IOD – 6
- Respiratory Viral Diseases – 14
- Hepatitis Viruses – 5
- Retrovirus Research – 10
- DNA Viruses – 16
- Vector-borne Viral Diseases – 4
- Method Development – 16
- Immunoregulation – 6

Site Visit Evaluation

- Program review
 - Assessment of progress on projects pursued since previous site visit
- Individual review
 - Consideration for promotion and tenure
- Evaluation of future directions