Meeting of the Blood Products Advisory Committee: Reclassification of HIV Serological and NAT Diagnostic and Supplemental Devices

July 19, 2018

J. Peyton Hobson, Ph.D.
CBER/OBRR/DETTD

Proposal

Reclassify HIV serology and NAT point of care and lab-based diagnostic and supplemental tests from Class III to Class II

Not included are HIV assays for:

- Blood donor screening
- Home use
- Viral load monitoring
- Phenotypic drug resistance

Question before the Committee

- The reclassification process depends on ability to mitigate risks to health through special controls
- Special controls are published as part of the new regulation– define what is necessary to develop a safe and effective new diagnostic or supplemental device
- In this context, please discuss the following:

Do committee members believe that special controls as described, in addition to general controls, are sufficient to mitigate the risks to health presented by reclassification of HIV serology and NAT point of care and laboratory-based diagnostic and supplemental devices?

Meeting overview

Background

HIV Diagnosis: A Review of the Past and Prospects for the Future
S. Michele Owen, Ph.D., CDC

Clinical Application of HIV Testing Technology: How They Are Used in the At-risk Communities David Hardy, M.D., Whitman-Walker Health

FDA presentations

Overview of Device Classification	Julia Tait Lathrop, Ph.D.
Current Status of HIV Diagnostic Devices	Anne Eder, M.D., Ph.D.
Overview of Proposed Special Controls	Julia Tait Lathrop, Ph.D.

Open Public Hearing

Question to the Committee	J. Peyton Hobson, Ph.D., OBRR
Open Committee Discussion	Angela Caliendo, M.D., Ph.D.

Acknowledgements

DETTD HIV reclassification working group

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OBRR

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