Introductory Remarks and Welcome

SBIA Webinar on Postmarket Reports
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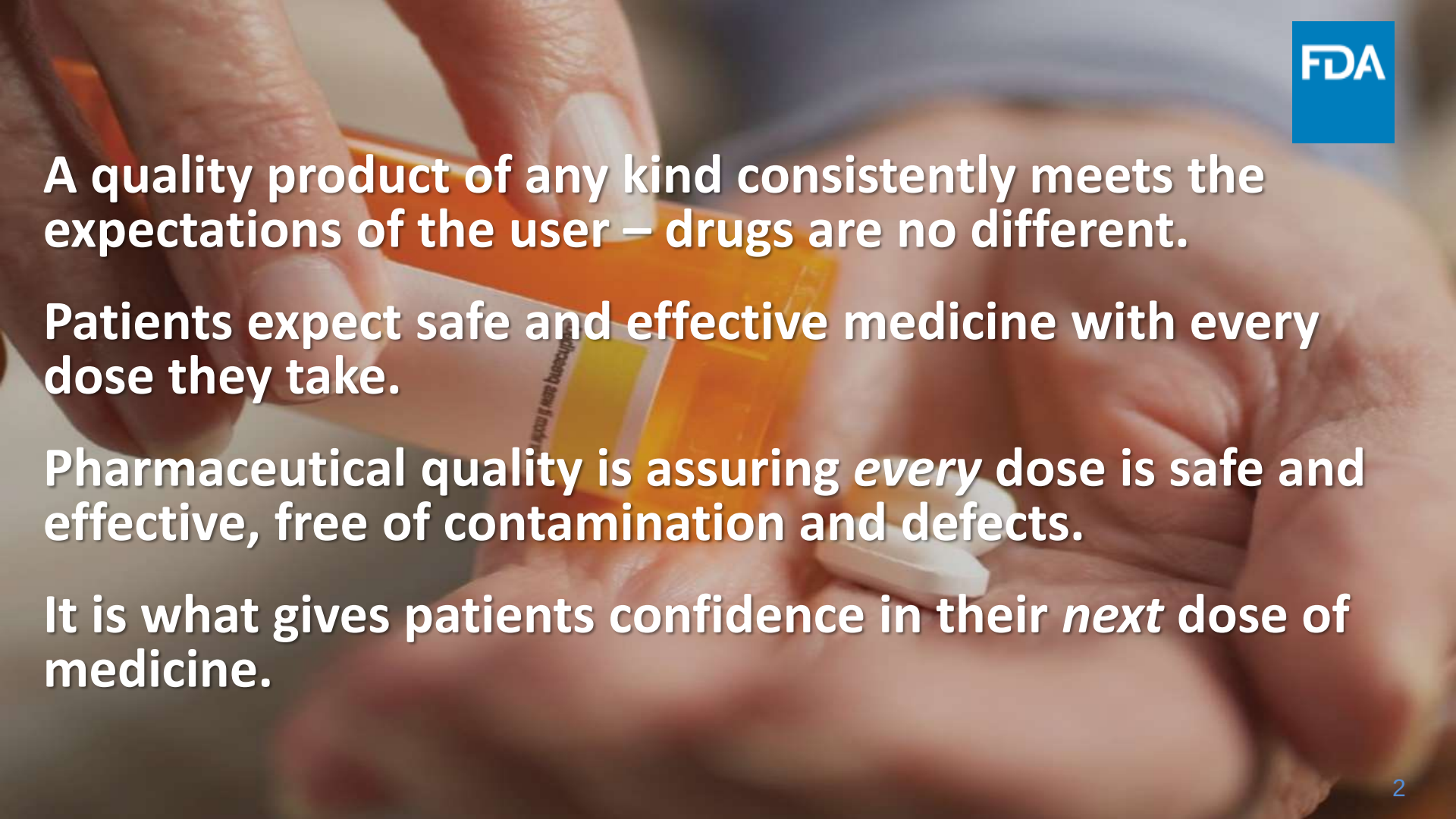

A quality product of any kind consistently meets the expectations of the user – drugs are no different.

Patients expect safe and effective medicine with every dose they take.

Pharmaceutical quality is assuring *every* dose is safe and effective, free of contamination and defects.

It is what gives patients confidence in their *next* dose of medicine.

Office of Quality Surveillance

VISION

- To be the global benchmark for pharmaceutical quality surveillance.

MISSION

- OQS turns intelligence into insights and actions to promote the availability of quality medicines for the American public.

Sleuths for Drug Quality!

- Help assure drug quality and availability
- Use intelligence, analytics, and CGMP assessments to:
  - Provide oversight of quality throughout drug lifecycle
  - Understand and model supply chains

Welcome! Today, FDA Will

- Provide a primer on postmarket reporting.
- Share insights on how FDA uses postmarket reports to reduce uncertainty, enable effective knowledge management, and make decisions.
- Encourage timely and accurate submission of Field Alert Reports (FAR) and Biological Product Defect Reports (BPDR).
- Emphasize that facilities are not penalized for postmarket reporting.

Goals for Attendees

- Understand:
  - Requirements for postmarket reporting
    - Who, what, when, why, and how
  - FDA's expectations for FAR and BPDR submissions
  - How FDA uses postmarket reports to facilitate risk-based decisions
  - How FDA is modernizing the assessment of postmarket reports


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