CDRH Guidance Development and Prioritization Workshop

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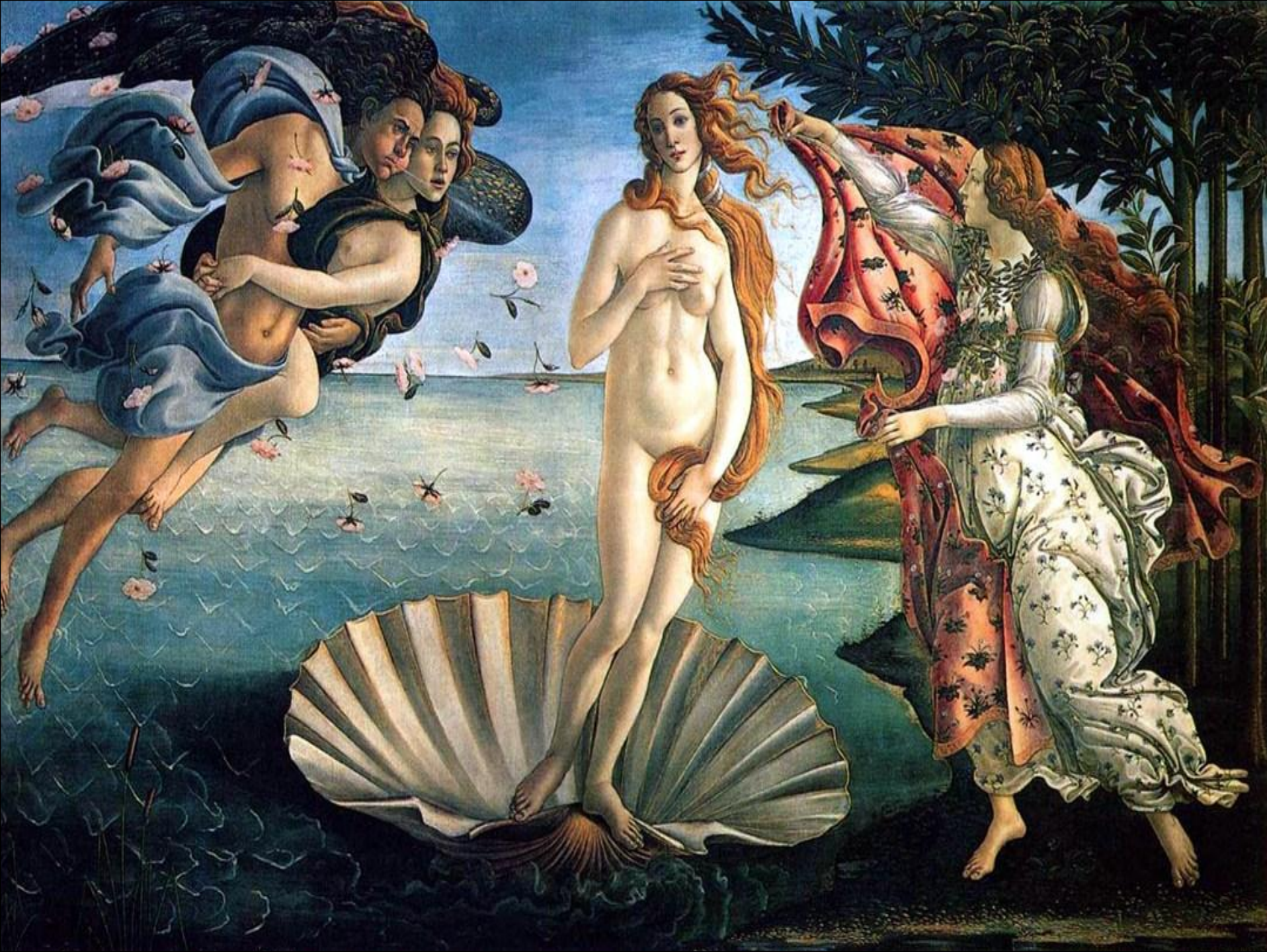

GGP 101

- Pre FDAMA, we had guidance on guidance.
- Section 701(h) of FDAMA:
  - Public participation
  - Non-binding nature
  - Guidance documents that set forth existing practices or minor changes in policy (level 2) and all other guidance documents (level 1)
- 21 CFR 10.115

GGP 101 – what is guidance?

- *Guidance documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue.*
- *Guidance documents include, but are not limited to, documents that relate to: The design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies.*

GGP 101-what isn't guidance?

- *Guidance documents do not include: Documents relating to internal FDA procedures, agency reports, general information documents.*

GGP 101 – Purpose of Guidance

- Transparency
- Consistency
- Predictability
- *Due Process*

Interest in Guidance

- FDAMA added section 701(h)
- FDASIA added:
  - Section 510(n)(2)
  - Section 701(h)(1)(C)(ii)
- Stakeholder interest:
  - Transparency
  - Status of drafts
  - Timeliness
  - Participation
  - Web site

GGP Workshop

Overview of GGP Workshop

- **CDRH guidance development process**
- **Guidance development best practices: FDA, CDRH and stakeholder perspectives**
- **CDRH guidance priorities and priority development**

Workshop Goals

Goals for GGP Workshop

- **Provide transparency into CDRH/FDA guidance process**
- **Promote dialogue on guidance process improvements**
- **Generate ideas for assessing impact of guidance**