

**IOM Committee on Review of Priorities of the
National Vaccine Plan
Stakeholder Workshop #1**

24 July 2008

FDA's Role in Vaccine Supply

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OFFICE OF VACCINES RESEARCH AND REVIEW: Mission Statement

Protect and enhance the public health by assuring the availability of safe and effective vaccines, allergenic extracts, and other related products.

FDA Regulatory Responsibilities

- **Review and evaluate INDs, BLAs, and amendments and supplements for safety and effectiveness**
- **Evaluate and test licensed vaccines and related products**
- **Inspect manufacturing facilities**
- **Conduct research related to the development, manufacture and testing of vaccines, and related products**
- **Develop policy and procedures for pre- and post-market review and evaluation**

Streamline **regulatory authority to ensure reliable production of safe and effective vaccines**

- **Increased utilization of regulatory pathways, e.g., accelerated approval and fast track designation.**
- **Enhanced collaboration and communication with manufacturers at all phases of product development.**
 - **Communicate regulatory expectations and promote the use of robust quality systems,**
 - **Provide examples of CGMP problems seen in the industry and the consequences of those problems,**
 - **Elicit meaningful dialogue with the industry and our foreign regulatory counterparts on CGMP issues for vaccines; and**
 - **Advise on design of facilities**

Streamline **regulatory** authority to ensure reliable production of safe and effective vaccines (continued)

- FDA Initiative- CGMPs for the 21st Century
 - Issuance of final guidance documents:
 - Sterile Drug Products Produced by Aseptic Processing, 2004, *includes recommendations on aseptic processing that begins earlier in the manufacturing process, such as the case with vaccines.*
 - Quality System Approaches to Pharmaceutical CGMP, 2006, *provides FDA's current thinking on QS principles, does not replace CGMP regulations but principles in guidance would assure CGMP compliance.*

Streamline **regulatory** authority (continued)

- Issued two Direct Final Rules that modified existing regulations to provide more flexibility to manufacturers and encourage innovations.
 - May 2004- Rule amended 21 CFR 600.11(e)(3) for work with spore-forming organisms,
 - March 2008- Rule amended 21 CFR 600.11(e)(4) for live vaccine processing.

Manufacturing and Quality

Continue efforts to modernize biologic and drug regulations and where possible to harmonize with other regulatory authorities

┆ 21 CFR Part 600-680

┆ Live Vaccine Processing Rule

┆ 21 CFR Parts 210-211

Enhance scientific tools and assessment for manufacturing – CBER research

Continue GMP Outreach to vaccine industry

Strategy #7: Improve product quality and availability through better manufacturing and production oversight

- ***Milestone:*** FDA will hire additional staff by FY09 to develop methods and procedures for monitoring supply and evaluating adequacy of supply, monitoring supply and taking steps to rectify as needed.
- ***Milestone:*** FDA will enhance outreach to the industry relevant to current Good Manufacturing Practice (CGMP) for vaccines by conducting and participating in meetings and workshops at least twice yearly to communicate regulatory expectations.

Strategy #7 (continued)

- ***Milestone:*** FDA will evaluate current regulations, guidance documents, policies and procedures within the next five years that are relevant to manufacturing and product evaluation to determine enhancements that could be made to improve product quality and availability via regulatory mechanisms.
 - ***Long-term:*** Publish revised regulations and issue guidance, and/or revise policies and procedures based on the evaluation.
- ***Milestone:*** FDA will engage with licensed and new manufacturers to establish or expand facility capacity; including meetings and strategically timed site visits to advise on CGMP practice and design of facilities.

Strategy #8: Support and assess adoption of new analytical and manufacturing control technologies and systems such as Process Analytical Technology (PAT) to enhance medical product quality.

- ***Milestone:* FDA will upgrade computer databases by the end of 2009 to track the number of meetings with industry as well as regulatory applications relevant to new manufacturing and control technologies and analytical methods for vaccine manufacturing.**
- ***Milestone:* FDA will assess the industry over the next five years to determine the impact of new analytical and manufacturing control technologies and systems.**

Strategy #8 (continued)

- ***Milestone:*** FDA will evaluate regulatory mechanisms (e.g., current regulations, guidance documents, policies and procedures) relevant to manufacturing and product evaluation to determine enhancements that could facilitate adoption of new analytical and manufacturing control technologies.
 - ***Long-term:*** Publish revised regulations and issue guidance, and/or revise policies and procedures based on the evaluation.

SUMMARY

- **Streamline the regulatory authority to ensure reliable production of safe and effective vaccines.**
- **Continue efforts to modernize biologic and drug regulations and where possible to harmonize with other regulatory authorities**
- **Enhance scientific tools and assessment for manufacturing – CBER research**
- **Continue GMP Outreach to vaccine manufacturers and other industries**
- **Encourage manufacturers to employ new technologies to include use of newer analytics, better manufacturing controls feedback systems etc., newer manufacturing systems - e.g., wave fermentation**

Conclusion

- **Regulatory processes should be:**
 - **Based on scientific knowledge and data**
 - **Facilitated by good communication, transparency, and timely decision-making**