INTEGRATION OF FDA FACILITY EVALUATION AND INSPECTION PROGRAM FOR HUMAN DRUGS: A CONCEPT OF OPERATIONS FY 2019 SUMMARY

In late 2017, the FDA's Center for Drug Evaluation and Research (CDER) and the Office of Regulatory Affairs (ORA) implemented a Concept of Operations (ConOps) agreement to more effectively manage the growing complexity of the pharmaceutical landscape and to meet new challenges by:

- Ensuring consistency, efficiency, and transparency in facility evaluations, inspections, and regulatory decision-making for marketing applications across FDA;
- Advancing strategic alignment across ORA and CDER functional units by creating clear roles and responsibilities;
- Improving FDA's operational capacity by enhancing collaboration between various CDER and ORA offices;
- Enhancing the quality of and increasing access to facility and regulatory decisional information across FDA; and
- Meeting user fee commitments and improving the timelines for regulatory, advisory, and enforcement actions to protect public health and promote drug quality, safety, and effectiveness.

Performance measures established by the ConOps agreement include that FDA (1) issue a final facility classification letter within 90 days of inspection closing*, and (2) complete regulatory actions for OAI facilities within 6 months of inspection closing*. In FY 2019, FDA issued 87% of final facility classification letters within 90 days of inspection closing and completed 74% of regulatory actions for OAI facilities within 6 months of inspection closing*. These measures allow FDA to provide transparency to facilities regarding inspection outcomes, which can enable timely implementation of corrective actions and continued access to high quality medicines, and offer industry faster access to data which could inform business decisions to help identify high quality suppliers. These efforts help provide concise and timely regulatory decisions which not only help to keep quality products on the market, but also to accelerate novel technologies and new therapies to market.

87%
of final facility classification letters issued within 90 days

74%
of regulatory actions completed within 6 months

This agreement has allowed FDA to more consistently improve the management of a pharmaceutical landscape experiencing growing complexity, to assure that the American public continue to have access to quality medicines.

*These metrics are specific only to Drug Quality Assurance inspections under CPGM 7356.002, and do not include sites classified through MRA.