INTEGRATION OF FDA FACILITY EVALUATION AND INSPECTION PROGRAM FOR HUMAN DRUGS: A CONCEPT OF OPERATIONS FY 2021 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.

This report summarizes FY 2021 metrics of the Concept of Operations agreement. Of note, from March 2020, the COVID-19 pandemic impacted the day-to-day operations at the FDA which impacted inspections conducted under the ConOps agreement. For example, travel restrictions have impacted the number of inspections conducted by FDA. In addition, resources needed to be diverted to the Pandemic Response.

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 2021, FDA issued 70% of final facility classification letters within 90 days of inspection closing and completed 48% of regulatory actions for OAI facilities within 6 months of inspection closing*. These measures enable 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 suitable suppliers. Communicating timely, complete, and concise decisions to manufacturers support the availability and accessibility of quality products, as well as the potential to accelerate novel technologies and new therapies to market.

70%
of final facility classification letters issued within 90 days

48%
of regulatory actions completed within 6 months

By integrating operations across CDER and ORA, FDA can more consistently improve the regulatory oversight of the pharmaceutical manufacturing landscape to assure that the American public continues to have access to quality medicines.

*These metrics are specific to Drug Quality Assurance inspections under Compliance Program 7356.002, and do not include sites classified by FDA through inspections conducted by foreign regulatory authorities under mutual recognition agreements.