9 ANDA Regulatory Approval Process

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The U.S. Food and Drug Administration (FDA) is organized into nine offices/centers: the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the National Center for Toxicological Research, the Office of the Commissioner, the Center for Tobacco Products, and the Office of Regulatory Affairs.

The CDER reviews the safety and efficacy of drug products. The Office of the Center Director oversees 12 offices, which include the Office of Pharmaceutical Science, the Office of New Drugs, the Office of Executive Programs, the Office of Surveillance and Epidemiology, the Office of Management, the Office of Regulatory Policy, the Office of Medical Policy, the Office of Counter-Terrorism and Emergency Coordination, the Office of Communications, the Office of Compliance, the Office of Translational Sciences, and the Office of Planning and Informatics. Additional information about the organization of the CDER can be found on the FDA website at www.fda.gov/cder.

Organizationally, the Office of Generic Drugs (OGD) is located within the CDER under the Office of Pharmaceutical Science. It consists of the following divisions: Chemistry, Bioequivalence, Clinical Review, Microbiology, and Labeling and Program Support. The following will provide a brief overview of the history of the OGD.

Nearly 30 years after its enactment, the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch–Waxman Amendments (HWA), has proven to be an effective piece of legislation. One outcome of this legislation is the increased availability of less expensive medications to millions of Americans. The HWA to the Federal Food, Drug and Cosmetic Act (FD&C) gave