As a student intern in the Division of Pulmonary and Allergy Products you will learn about the drug development process (Pre-IND, IND, and NDA stages), as well as the overall organizational structure of CDER and FDA. You will have the opportunity to observe the drug review process as conducted by a drug review team, which is composed of a regulatory project manager and several scientific review disciplines, through attendance at internal meetings and meetings with pharmaceutical industry. Additionally, you will learn what the role and responsibilities of a regulatory project manager are as part of a drug review team. Through this experience, you will also learn about the wide variety of opportunities available for pharmacists at FDA.

Division of Pulmonary and Allergy Products

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The ultimate goal of the Division is to approve safe and effective pulmonary and allergy drug products for marketing. In order to help achieve this goal, the Division works with its counterparts in pharmaceutical industry throughout the new drug development process. Sponsors are encouraged to interact with the division during all stages of drug development.

The typical drug review team includes the following representatives:

- Regulatory Project Manager: Reviews regulatory aspects of IND and NDA submissions; serves as a liaison between the Division's review team and pharmaceutical industry.
- Medical Officer: The head of the review team. Reviews all clinical studies and oversees the review of all aspects of the IND application or NDA.
- Pharmacologist/Toxicologist: Reviews all nonclinical studies.
- Chemist: Reviews chemistry, manufacturing and controls data/specifications.
- Biostatistician: Performs statistical analyses of clinical studies.
- Clinical Pharmacologist: Reviews the pharmacologic and biopharmaceutical aspects of clinical studies.

The following groups are often consulted during the application review process:

- The Pulmonary and Allergy Drugs Advisory Committee (PADAC)
- The Division of Drug Marketing, Advertising, and Communications
- The Division of Medication Errors and Technical Support
- The Division of Drug Risk Evaluation
- The Division of Surveillance, Research and Communication Support
- The Office of Generic Drugs
- Study Endpoints and Labeling Development Team
- Division of Scientific Investigations
- Pediatric and Maternal Health Staff
- Office of Nonprescription Products
- New Drug Microbiology Team
- Botanical Review Team
- Controlled Substance Staff
- Office of Chief Counsel
- Office of Regulatory Policy

The Division of Pulmonary and Allergy Products reviews Investigational New Drug applications and New Drug Applications for drugs in the following classes, and for the following disease states/conditions, including, but not limited to:

Disease states/conditions:

- Asthma, Prevention and Treatment
- Anapylaxis/Anapylactoid reactions
- Allergic Rhinitis, Seasonal and Perennial (SAR and PAR)
- Bronchospasm, associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.
- Bronchopulmonary Dysplasia (BPD)
- Chronic Idiopathic Urticaria (CIU)
- Chronic Obstructive Pulmonary Disease (COPD)
- Cystic Fibrosis (CF)
- Hereditary Angioedema
- Nasal polyps
- Respiratory Distress Syndrome (RDS)
- Pulmonary Fibrosis
- Vasomotor Rhinitis

Drug classes:

- Anticholinergics
- Antitussives
- $Beta_2$ agonists, short-acting and long-acting

- Corticosteroids
- Histamine H_1 receptor antagonists
- Leukotriene receptor antagonists (LTRAs)
- 5-Lipoxygenase inhibitors
- Lung surfactants
- Monoclonal antibodies
- Protein drug products
- Sympathomimetic amines