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FOOD AND DRUG ADMINISTRATION UPDATE

CURRENT ACTIVITIES AND ISSUES

Background

One of the missions of the FDA is to evaluate new therapeutic agents for safety and efficacy. Investigational new drug (IND) applications for CFS are reviewed by a multi disciplinary team in the Division of Special Pathogen and Transplantation Products (DSPTP) within the FDA's Center for Drug Evaluation and Research (CDER), or in other appropriate divisions within the FDA. FDA drug review teams have diverse scientific and regulatory expertise and are composed of physicians, pharmacologists (toxicologists and clinical pharmacologists), chemists, microbiologists, mathematical statisticians and consumer safety officers.

FDA works closely with sponsors of therapeutic agents throughout the drug development process. Although FDA is unable to comment publicly on the status of specific drug applications prior to their approval, the following overview summarizes the Division of Special Pathogen and Transplantation Product's typical involvement during drug development. (The actual drug review process in FDA may vary from this brief overview and will depend on the nature of the investigational agent, the sponsor, and the responsible reviewing division within FDA).

- During the early (preclinical) drug development and prior to testing in humans, sponsors are encouraged to discuss their plans with a "pre-IND" team of FDA scientists. The Pre-IND Consultation Program is open to all sponsors and was developed to facilitate safe and timely drug development, particularly in areas that are innovative and/or deal with serious and life-threatening illnesses.
- Once an IND has been filed, FDA scientists work closely with drug sponsors to insure that proposed clinical trials are safe for patients and are designed appropriately to meet their stated objectives. The drug sponsor and other clinical researchers are responsible for conducting the clinical trials.

- As studies are completed, FDA scientists review study results and provide feedback to sponsors on any remaining requirements prior to submission of a New Drug Application (NDA).
- Upon receipt of a NDA, the multi disciplinary scientific team at FDA reviews all of the data therein to ascertain whether the new product is safe and effective for its intended use.
- Once a drug is approved, FDA remains actively involved in post-marketing surveillance of drug safety through ongoing review of spontaneous adverse event reports and conduct of pharmacoepidemiologic studies.

ACCOMPLISHMENTS

For the past year, the Office of New Drugs has been located on its new campus in Silver Spring, Maryland, which allows all has facilitated productive interactions among the review specialties. Coinciding with this move the Office of New Drugs was reorganized, and the Division of Special Pathogen and Immunologic Drug Products became the Division of Special Pathogen and Transplantation Products, within the newly renamed Office of Antimicrobial Products. The name changes reflect the incorporation of many biologic therapeutics within the new drug review divisions. This has not changed how products for CFS are reviewed in the Agency. The same divisional team is still involved with the products for CFS; however, the opportunity to consult other divisions with expertise in particular areas of interest for CFS has been enhanced.

- Investigational products continue to be evaluated in the treatment of CFS and are in various stages of development under INDs in DSPTP.
- FDA cannot publicly comment on the status of any sponsor's drug development program. However, under the FD&C Act substantial evidence of safety and efficacy from adequate well-controlled trials is required for marketing approval and such evidence should be available as part of any New Drug Application.
- The Pre-IND Consultation Program in the Office of Antimicrobial Products in FDA's Center for Drug Evaluation and Research, in collaboration with the Division of Special

