CHRONIC FATIGUE SYNDROME ADVISORY COMMITTEE
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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 Pathogen and Transplantation Products, has also provided guidance to assist investigators and sponsors in submitting successful IND applications to evaluate investigational drugs in the treatment of CFS.

- In addition to ongoing involvement in various stages of CFS drug development, FDA has been proactive in drug development:

  - FDA has ongoing involvement with the CFSAC and participates in all activities.

  - FDA maintains an active role in education about its function in drug development through publications and public speaking.

  - FDA's Office of Special Health Issues works closely with the Division of Special Pathogen and Transplantation Products and facilitates appropriate liaisons for individuals with CFS and their advocates. This Office also provides the public with information on the drug approval process and access to investigational drug products.

FY 2007 ACTION PLAN

- FDA is committed to providing timely review of IND study protocols and study reports for CFS drug therapies. FDA will continue to work closely with sponsors of CFS drug therapy at all stages of drug development.

- As the new need arises, FDA will update the Antiviral Drugs Advisory Committee on progress in the field of CFS drug development. Advisory Committee discussions of CFS-related issues will include representation by an expert in the field of CFS and a CFS patient advocate.

- FDA will continue to participate in activities with the CFSAC.

- FDA will continue to actively participate in CFS meetings and workshops in order to develop and delineate requirements for clinical trials.

- FDA will continue to promote development of CFS clinical

trial endpoints, through work with sponsors and researchers.

- FDA's Office of Special Health Issues will work closely with the Division of Special Pathogens and Transplantation Products and will facilitate appropriate liaisons for individuals with CFS and their advocates.

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http://www.fda.gov/default.htm

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