

## PROGRAM FOR STUDENT VOLUNTEER

### OFFICE OF ORPHAN PRODUCTS DEVELOPMENT (OPD)

I. A student participating in the FDA student volunteer program within the Office of Orphan Products Development (OPD) will become generally familiar with FDA, and more specifically familiar with the mandate of OPD and how it implements the provisions of the Orphan Drug Act of 1983. This will be accomplished by the student participating in the activities of OPD and FDA. The student will receive one on one interviews with FDA personnel who have acquired the educational credentials which the student is currently pursuing. Within OPD the student will learn and participate in the designation and grant activities which are the foundation of the activities within the Office.

A. The Orphan Drug Act and Orphan Regulations

The student will learn the history behind the development and approval of the Orphan Drug Act. He/she will also learn the regulation development and implementation process. This will provide insight into the specific activities within FDA and consumer groups on orphan related issues. The student will participate in the regularly scheduled meetings in OPD in order to better understand these issues.

B. Orphan Drug Designation

The student will learn the orphan drug designation process and the importance of product designation in orphan drug development. The student may be able to review and evaluate an orphan designation application under the close supervision of his/her preceptor.

C. Orphan Grants

The student will learn the orphan grant process and the importance of orphan grants in orphan drug development. The student may be able to participate in the grant review and site visit processes in order to better understand the clinical trials process and its relevance in drug development in general.

II. The student will provide a benefit to the Office of Orphan Products Development by:

A. Providing staff members with the results of literature searches.

B. Providing staff members with the summary results of data tabulations.

C. Providing staff members with findings upon completion of a special project.

(Note: The student will be closely observed so that he/she will not be exposed to confidential

material during his/her stay at FDA.)

- III. The Office of Orphan Products Development will provide a benefit to the student by offering the following.
  - A. FDA orientation; particularly with the Centers for Drug and Biologic Evaluation and Research.
  - B. FDA library orientation.
  - C. Office of Orphan Products Development Orientation.
  - D. Orientation to Civil Service and Commissioned Corps career opportunities.
  - E. Miscellaneous (drafting letters/memos; proofreading and editing non-confidential material).
- IV. The above will be provided by OPD staff members. Visits to other offices within the Agency or to other places of professional interest will be arranged by the student's preceptor as time permits.