The Center for Biologics Evaluation and Research (CBER) is one of six centers within FDA, and is responsible for the regulation of biologically-derived products, including blood intended for transfusion, blood components and derivatives, vaccines and allergenic extracts, and cell, tissue and gene therapy products. The Office of Communication, Training and Manufacturers Assistance (OCTMA) is one of nine CBER Offices and is charged with: 1) maintaining and developing effective channels for both internal and external communications; 2) managing the Center's professional and management training programs; 3) serving as the Center liaison for providing guidance to information requests from manufacturers, healthcare providers and consumers; and 4) directing the Center's Freedom of Information, access litigation and consumer and professional outreach activities. During the rotation, the student will interact with a variety of professionals within OCTMA and have the opportunity to observe and/or participate in various activities related to Division and/or branch responsibilities.

The student will have an opportunity to:
1) Learn about FDA regulated biological products
2) Research and evaluate policy related to the regulation of biologics
3) Assist with internal/external information requests/inquiries
4) Attend Advisory Committee and other meetings related to CBER products (as scheduled)

Upon completion of the rotation, the student should be familiar with: 1) CBER products and the FDA organization; 2) sections of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act; 3) sections of the Code of Federal Regulations (CFR); and 4) FDA guidance documents related to the regulation of biologics.

Website:
http://www.fda.gov/cber/about.htm