DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Dear Sponsor,

As you may know, the regulatory responsibility, review and continuing oversight, for many biologic therapeutic products will be transferred from the Center for Biologics Evaluation and Research (CBER) to the Center for Drug Evaluation and Research (CDER). This change in regulatory responsibility will result in the transfer of your IND, IDE, BLA, or NDA if it belongs to one of the following product classes:

- Monoclonal antibodies for in-vivo use;
- Cytokines, growth factors, enzymes, immunomodulators, and thrombolytics;
- Proteins intended for therapeutic use that are extracted from animals or microorganisms, including recombinant versions of these products (except clotting factors)
- Other non-vaccine therapeutic immunotherapies

The following product classes will remain at CBER:

- Viral-vectored gene insertions (i.e., "gene therapy")
- Products composed of human or animal cells or from physical parts of those cells
- Allergen patch tests
- Allergenics
- Antitoxins, antivenins, and venoms
- In vitro diagnostics
- Vaccines, including therapeutic vaccines
- Toxoids and toxins intended for immunization
- Blood, blood components and related products

Products that are used solely as a constituent in a manufacturing process for a biologic (e.g., protein to activate somatic cells) should be described in the IND for the investigational product (e.g., somatic cells) or in a drug master file submitted in support of the IND.

To determine which Center will be working on your files, we have posted lists of products remaining and being transferred. You may access these lists, which are organized by file type and tracking number at http://www.fda.gov/cber/transfer/transfer.htm . Questions about file assignment should be directed to: CBER's Office of Communication, Training and Manufacturers Assistance by telephone 800-835-4709, 301-827-1800, fax 301-827-3843, or email to MATT@cber.fda.gov.

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For those products being transferred, the change in review responsibility will be effective June 30, 2003. In most cases, the Regulatory Project Manager and assigned reviewers will not change since many of these staff will be reassigned to CDER. For the time being, all applications and correspondence, including adverse event reports and biological product deviation reports, should continue to be addressed to the CBER Document Control Center until further notice. The correct mailing address for all files is as follows: CBER Document Control Center (HFM-99), 1401 Rockville Pike, Suite 200N, Rockville, Maryland 20852-1448.

If your file is being transferred to CDER, you will be advised of any changes in procedures when they occur.

We hope that the goals of this product consolidation will benefit our stakeholders and we look forward to a successful transition to this new alignment.

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