DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

User Fee Correspondence

OCT 1 1997

Dear Colleague:

The Prescription Drug User Fee Act (PDUFA) of 1992 (Public Law 102-57 1) amended the Federal Food, Drug, and Cosmetic (FD&C) Act to authorize the Food and Drug Administration (FDA) to collect user fees from applicants who submitted certain new drug applications, biological applications, and supplements on or after September 1, 1992. An extension of PDUFA is under consideration by Congress, as is the Agency's appropriation for 1998. FDA is now operating under a continuing resolution that expires October 23, 1997. Under the continuing resolution, FDA is authorized to continue to collect user fees for applications, products, and establishments at the Fiscal Year (FY) 1997 rates and to review applications in accordance with the FY 1997 PDUFA performance goals. Under its original PDUFA authority, FDA will continue to collect fees due for periods prior to October 1, 1997, including the second half of application fees for applications submitted prior to October 1, 1997.

If legislation is passed that allows FDA to collect fees under a new PDUFA program, invoices will be issued for any additional fees authorized under the new legislation, refunds will be made if appropriate, and we will provide information on how to submit user fees for new applications and supplements after that time. We will notify you of any further changes in this program including any changes in the performance goals.

Thank you for your support of the user fee program. We continue our commitment to work jointly with industry and Congress towards reauthorization of the PDUFA.

Sincerely,

A. Robert Miller
Acting Director
Office of Financial Management