Other Legislative Items

Follow-on Protein Products

For FY 2009, the Administration will seek new statutory authority to allow FDA to approve abbreviated applications for certain biologic products licensed under the Public Health Service Act (PHS Act). Currently, no abbreviated pathway for these products, commonly referred to as follow-on protein products, exists in the PHS Act.

The legislative proposal will include necessary provisions to ensure the safety and effectiveness of these biologic products for patients. The proposal will include a predictable and public guidance process for licensing follow-on protein products under the PHS Act. The proposal will prescribe the type of data required for FDA to review applications for follow-on protein products and will require labeling for the safety concerns related to the interchangeability of these products. In addition, the proposal will include adequate intellectual property protections to preserve continued robust research into new and innovative life-saving medications. The Budget proposes a new authority for FDA to approve follow-on protein products through a new regulatory pathway that protects patient safety, promotes innovation, and includes a financing structure to cover the costs of this activity through user fees

Direct to Consumer Television User Fees

Title I of the Food and Drug Administration Amendments Act (FDAAA) reauthorizes the Prescription Drug User Fee Act. Title I of FDAAA also authorizes user fees to support the review of direct to consumer television advertisements (DTC-TV). However, the law authorizing DTC-TV fees contains a condition requiring that FDA collect a threshold amount of fees within 120 days. Because the FDA appropriations act for FY 2008 did not appropriate fees for the DTC-TV program, FDA could not meet the 120-day requirement.

The budget for FY 2009 contains user fees to support the review of direct to consumer television advertisements, as authorized by PDUFA. The Administration will work with Congress to modify the 120-day requirement in FDAAA to ensure that FDA can operate the DTC-TV program in FY 2009.

Earmarks

Several FDA projects that received funding in FY 2007 and FY 2008 were considered presidential earmarks. If funds are available for these activities in FY 2009, projects will be awarded through a merit-based competition.