

## **Proposed revisions to ADUFA**

### **Section 105**

“(E) The Secretary shall make summaries of the information reported under this paragraph publicly available, that—

“(i) include information about the volume of antimicrobial drugs sold categorized by medical importance, dosage form, target animals to the maximum extent practicable, and marketing status, and may include other cross-tabulations;

“(ii) assess the effectiveness and industry compliance with FDA Guidance for Industry 209 and 213, or any subsequent guidance, using valid and robust performance metrics.

(F) The summaries provided under subsection (E) of this section—

“(i) shall be reported in a manner consistent with protecting both national security and confidential business information; and

“(ii) may categorize animal drugs with fewer than 3 distinct sponsors as not independently reported, provided that the Secretary certifies that publishing such information would jeopardize confidential business information.”

### **New Section**

#### **SEC. 109. ENHANCED DATA COLLECTION STRATEGY**

(a) The Secretary shall finalize regulations pursuant to the Advanced Notice of Proposed Rulemaking entitled “Antimicrobial Animal Drug Distribution Reporting (77 Fed. Reg. 44177 (July 27, 2012)) within two years of the enactment of this section.