

FDA Secures Full Industry Engagement on Antimicrobial Resistance Strategy

Issues First Six-month Progress Report to Update Public on Current and Pending Drug Label Changes

June 30, 2014

The U.S. Food and Drug Administration announced today the first of its progress reports on its strategy to promote the judicious use of antimicrobials in food-producing animals. All 26 drug manufacturers affected by Guidance for Industry (GFI) #213 have now agreed to fully engage in the strategy by phasing out the use of medically important antimicrobials in food-producing animals for food production purposes and phasing in the oversight of a veterinarian for the remaining therapeutic uses of such drugs. While GFI #213 specified a three-year timeframe (until December 2016) for drug sponsors to complete the recommended changes to their antimicrobial products, some sponsors have already begun to implement them.

FDA is committed to updating the public on the progress that drug sponsors have made in aligning their products with GFI #213 and intends to do so on a six-month basis. FDA's progress reports will summarize current and pending actions taken by sponsors to align with the guidance, including the type of action (e.g., withdrawal, change in marketing status) and, when possible without revealing confidential business information, the type of animal for which the drug is approved for use and the type of application (pioneer, generic, combination).

As of June 30, 2014, FDA reports the following progress in the animal health industry's engagement in GFI #213:

- The last sponsor, Pharmaq AS, has agreed in writing to engage in the judicious use strategy, and has consented to allow FDA to publicly acknowledge its participation. With this addition, all 26 sponsors of 283 affected applications have now confirmed in writing their intent to engage with FDA as defined in GFI #213 and have given FDA consent to identify them as participants. Please see FDA's [March 26, 2014 Update](http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390738.htm) (<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390738.htm>) for a list of companies that had previously committed to the strategy.
- There have been two published label changes, one to withdraw a production claim and one to change a product's marketing status from over-the-counter to available by prescription only. These changes are documented in the online chart of [Applications Affected by GFI #213](http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm) (<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm>), and FDA will continue to update this chart in real time when label changes are approved.
- One additional drug label change is currently pending. The change is from over-the-counter marketing status to prescription status. More details about the product and the change in labeling will be available after the paperwork is complete.*

- 31 approvals for affected products have been withdrawn to date, and there are no drug approval withdrawals currently pending. After an approval is voluntarily withdrawn, those product(s) can no longer be marketed or sold in the United States.

*The level of summary detail provided in this update for pending supplemental applications is limited by the need to protect confidential business information (CBI). To avoid revealing CBI, either directly or indirectly, the level of summary detail provided for future updates regarding GFI #213-related pending actions may change as this voluntary initiative progresses and the pool of affected applications gets smaller. Given the small number of pending changes and completed changes at this time, FDA cannot provide more information about the type of drug being affected (e.g., application type, species, indication, etc.) in this update without revealing protected information.

FDA will continue to work with the animal pharmaceutical industry, animal producers and the veterinary community to address antimicrobial resistance and preserve the effectiveness of antimicrobials of human health importance.