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Latest FDA User Fee Bill Unlikely To Include Major Reforms

By **Rachel Slajda**

Law360, New York (March 25, 2013, 7:51 PM ET) -- This year's U.S. Food and Drug Administration animal-drug user fee reauthorization won't come nearly as loaded with FDA reforms as past user fee bills, experts say, warning the legislation is unlikely to build the necessary political momentum to push through the more controversial measures that drugmakers and public health groups would like to see.

The animal-drug user fee bill, S. 622, was approved by the Senate Health, Education, Labor and Pensions Committee in a voice vote Wednesday. The bill only reauthorizes the fees for brand-name and generic veterinary and livestock drugs and currently has no unrelated provisions that would affect the drug industry.

The committee's leaders rejected proposed amendments such as one that would require more extensive reporting by drugmakers on the use of antibiotics in livestock feed. The provision, proposed by Sens. Dianne Feinstein, D-Calif., and Kirsten Gillibrand, D-N.Y., has the support of public health groups that say the overuse of antibiotics in livestock is contributing to increasing antibiotic resistance in humans. Such efforts are opposed by animal-drug makers.

Still, the amendment, which Feinstein and Gillibrand say they will continue to push for, could have the best chance out of any of the other reforms that the industry or the FDA is looking for this year. Proposals like a nationwide track-and-trace system for drugs, new authority for the FDA to oversee compounding pharmacies, or the repeal of a $29 billion tax on medical devices are too controversial to get much traction, experts say.

“I think this is one bill that should get through unscathed by other provisions,” Stephen Mahinka, chair of Morgan Lewis & Bockius LLP's life sciences practice, said of the user fee bill.

The animal-drug industry is hoping the bill gets through Congress as clean as possible. A spokesman for industry group the Animal Health Institute told Law360 that the group was happy the bill had gotten through committee without amendments and hoped for “continued momentum.”

That's a departure from last year's FDA Safety and Innovation Act, which reauthorized the user fees for human drugs and devices and included a variety of additional provisions, such as incentives for new antibiotic development and a directive to the FDA to release comprehensive guidelines on social media.

In a gridlocked Congress, must-pass legislation like reauthorizing user fees tends to attract a lot of extra provisions that wouldn't pass on their own. FDASIA, which had widespread support from every segment of the industry, the FDA and most lawmakers, became a vehicle for many provisions, although the most controversial, such as track-and-trace, were scrapped.

But although the current bill, known as the Animal Drug User Fee Act, has industry and lawmaker support, it affects a smaller sector of the industry and is therefore more susceptible to getting defeated under the weight of controversial measures.

“The difference, I would say, is there was a lot more riding on FDASIA. At the end of the day, it's just a small subset of folks that care about the animal-drug user fee,” said Chuck Clapton, a partner at Hogan Lovells and a former health policy director for the Senate HELP committee. “You don't have that universe of folks pushing it.”

That's not to say lawmakers won't try. The bill still has to make its way through the House Energy and Commerce Committee, and then face votes on the House and Senate floors. The Republican leaders of the House Committee's health panel reportedly suggested this week that they may try to use ADUFA for some FDA reforms they'd like to see.

One cited by Rep. Michael Burgess, R-Texas, is additional incentives to get drug companies to invest in new antibiotics, according to Modern Healthcare. New antibiotics are another response to the growing problem of antibiotic resistance in humans, although incentives are a different approach from Feinstein and Gillibrand's amendment.

And Feinstein and Gillibrand will continue to lobby for the inclusion of their amendment, which would require the FDA to publish detailed information about the volume of antibiotics sold, according to a Senate aide.

“Both senators are continuing to work with the chairman and ranking member to find a viable path forward and are hopeful that they can reach an agreement soon,” the aide said.

Getting additional reporting will continue to be a tough sell, however, because of strong opposition from the industry.

“That is a big issue. If you start to have to monitor this, report this, control this, it increases costs and potential liability quite substantially,” Mahinka said. “It's not something [drugmakers] want to agree to.”

--Editing by Elizabeth Bowen and Jeremy Barker.