



# Biotech Daily

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## **ANATARA: FDA OKAYS DETACH-TREATED PIGS 'FOR HUMAN FOOD'**

### ANATARA LIFESCIENCES

Anatara says that the US Food and Drug Administration has provided “complete” letter for the technical section of its human food safety submission.

Anatara is developing its pineapple stem, bromelain-derived Detach as a non-antibiotic treatment for pig and human diarrhoea.

The company said that the letter “confirms that the US Food and Drug Administration is satisfied that food products from animals treated using Detach will be safe for human consumption”.

Anatara said the human food safety submission was “a major component of a new animal drug application (NADA) which is currently underway and is necessary for enabling the marketing of Detach in the US”.

The company said that the technical section included an assessment on whether Detach would contribute to antimicrobial resistance.

Anatara executive chairman Dr Mel Bridges said that the safety of edible products from drug-treated, food-producing animals was “a critical part of the US drug approval process, so receipt of the complete letter is a core step for the entry of Detach into world markets”.

“The efficacy, overall safety and manufacturing information required for the approval of human and animal drugs is very similar, but the safety of a drug targeted at food-producing animals must undergo an additional level of stringent review to ensure that there are no residual safety issues for the human consumer,” Dr Bridges said.

Dr Bridges said that the human food safety section of the registration process could take three to six years to complete and up to 70 percent or \$8 million of expenditure for a new drug, so “the fact that Anatara has achieved an outcome within three years of opening our investigational new animal drug application is an outstanding result and speaks to the strong safety profile we’ve seen for Detach in our trials,”.

Anatara was up fell two cents or 1.1 percent to \$1.77.

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