

**From:** Mirabilis  
**Sent:** Monday, 29 August 2016 4:29 PM  
**To:** Curtis, Imogen  
**Subject:** PC INQUIRY into REGULATION IN AGRICULTURE Fwd: Response to your Case 00094397: [ ref:\_00D60KbN0.\_500t03Ugo2:ref ]

**Re: Our submission - additional information - PC INQUIRY into REGULATION IN AGRICULTURE.**

Dear Imogen,

To assist with our submission, we requested contact with the US Federal Drug Administration (US FDA). "FCIC Inquiry" <[fcicinquiry@fda.hhs.gov](mailto:fcicinquiry@fda.hhs.gov)> <[fcicinquiry@fda.hhs.gov](mailto:fcicinquiry@fda.hhs.gov)>

We noted discrepancies / errors in the FDA website and raised valid questions. Because of the failure to get answers from them at ground level, we asked to be referred to the departmental head. There has still been no response.

The evasiveness, lack of transparency, the curious difficulties encountered in attempting to have questions answered by the FDA, and the outright failure of the FDA to respond to valid concerns in a reasonable period of time is noteworthy. It confirms the lack of trust and confidence in the US FDA felt by so many of us here in Australia - a disquiet and general uneasiness reportedly shared by millions of Americans. That lack of trust spills over to our Australian regulators, which appear to rely heavily on the US FDA.

We also note that the US FDA, which has offices in many countries including our own, cannot be approached by the Australian general public / consumers - only by corporations it seems. This is a further reflection on the very unsatisfactory *status quo*.

Please include this observation in our submission.

Kind regards,  
Meg & Paul Wilson  
Perth WA

----- Forwarded Message -----

**Subject:**Response to your Case 00094397: [ ref:\_00D60KbN0.\_500t03Ugo2:ref ]

**Date:**Wed, 24 Aug 2016 17:10:03 +0000 (GMT)

**From:**"FCIC Inquiry" <[fcicinquiry@fda.hhs.gov](mailto:fcicinquiry@fda.hhs.gov)> <[fcicinquiry@fda.hhs.gov](mailto:fcicinquiry@fda.hhs.gov)>

**To:**



This message is being sent in response to the following submitted inquiry:

Attention FDA Officer,

I emailed FDA from Australia, with a number of valid queries and requests. This response below from FDA is unsatisfactory and inappropriate. Obviously I am not a US citizen and am unable to participate in a petition. Please refer me to your supervisor or departmental principal as soon as possible.

Mrs M Wilson .

\*\*\*\*\*

FDA response today, 24 August 2016.

The Food and Drug Administration's (FDA) Food and Cosmetic Information Center (FCIC)/Technical Assistance Network (TAN) has prepared a response for case number 00093992.

Response: Hello

I understand your concern. You may file a citizen petition with the FDA. Here is link to do that

<http://www.fda.gov/regulatoryinformation/dockets/ucm379450.htm>

Thank you for contacting FDA's FCIC/TAN.

The Food and Drug Administration's (FDA) Food and Cosmetic Information Center (FCIC)/Technical Assistance Network (TAN) has prepared a response for case number 00094397.

Response: Hello

Anyone can file a citizens petition. You do not need to be a U.S. Citizen. Please see 21 CFR 10.30

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm><http://>

In addition, you may contact the FDA labeling office at 240-402-2373

Thank you for contacting FDA's FCIC/TAN.

This communication is intended for the exclusive use of the inquirer and does not constitute an advisory opinion (21 CFR 10.85(k)). Also note that this response is not intended to be a comprehensive list of all applicable requirements. Please check FDA's web page ([www.fda.gov](http://www.fda.gov)) regularly for guidance reflecting our current thinking. Additional information on FSMA can be found on FDA's FSMA web page ([www.fda.gov/fsma](http://www.fda.gov/fsma)). This communication may contain information that is protected, privileged, or confidential. If you have received it in error, please immediately delete all copies.

\*\*Please do not reply to this email box. If you would like to submit a follow-up question or need clarification to this inquiry, please click here <http://cfsan.force.com/InquiryPage> and reference this inquiry's case number.

