

Consultants Update

COVID-19

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Discussion Topics

- FDA Food Production Inquiries
- FDA Drug Audit Inquiries
- Hand Sanitizers

FDA Food Production Inquiries

- Email from FDA
 - Subject: Re: Food and Drug Administration - Food Facility Registration questions
- Some simple questions and some intrusive questions
 - What is the number of full time/part time employees ...
 - What is the total annual sales for this facility (gross)?

FDA Food Production Inquiries

- In the past, the FDA has de-registered facilities... temporarily
- CGA has contacted FDA
 - No de-registrations
 - More details later

FDA Drug Audit Inquiries

- Similar to the food questionnaire
- FDA Form 4003 - ~7 pages of questions
- Appears to be audit preparation
- Please call if you get the request

Hand Sanitizers

- FDA Guidance and recipe – easier to produce hand sanitizers
- Not so easy....
 - Registration operations change (Rx & OTC)
 - New label listing
 - Raw material availability
 - Formula for ethanol – ATF regulated (Formula 40A or 40B) – Do not use other denatured ethanols
- More details available

Contact Info

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