



## **Guidance for Distilleries: Adverse Event Reporting to the FDA**

Adverse event reporting may sound a bit intimidating. The purpose of the FDA is to have a documented process for all drugs (pharmaceutical and over-the-counter) to ensure that consumers have a way to submit any unanticipated reaction to using or taking the drug.

The FDA considers the Hand Sanitizer an over-the-counter drug and as such, these guidelines will make sure that if you do have any consumer contact you with an adverse event, you can report this to the FDA in a straightforward and concise way.

- **What is an Adverse Event?**

Any undesirable event that is associated with the use of a drug or biological product in humans whether or not considered product-related by the applicant. For example: rash, burn, skin peeling, skin cracking, redness, etc. If a consumer is making a complaint, assume it is an Adverse Event. It's better to report it and let the FDA decide.

- **What information is required to report an Adverse Event?**

- The patient
  - Patient identifier
    - Note: Do NOT use any personally identifiable information. Use their initials instead of name. DO NOT get any sensitive data such as SSN.
  - Age/DOB
  - Gender
  - Weight
  - Ethnicity or race
- The product used
  - Picture of product and bottle if possible
  - Batch date or date of manufacture
- The specific adverse event
  - Outcome attributed to adverse event, e.g. What happened? What is the complaint?
  - Description of event
  - Date of event
  - Date of report of Adverse Event
  - Any other relevant history including pre existing medical conditions

- **How is an Adverse Event reported to the FDA?**

- o Reports must be submitted to the FDA of FDA Form 3500.
- o Here is the website:  
<https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>

- **How does a consumer submit an Adverse Event?**

- o All distilleries MUST have a way for consumers to contact them to report any adverse events.
- o The label MUST include the name and contact information of the manufacturer (distillery). Contact information can be either email or phone:
  - Email: This could be a separate email domain that is advertised on the hand cleanser bottles, e.g. "questions@distilleryname.com"
  - Dedicated Phone number
    - This cannot be your general phone number but it could be an extension or if possible, set up an 800 number. As an example, Purell puts "Questions contact us at 1-888...".
- o Someone on the distillery team must check this email and/or phone number to ensure a proper response time
  - Note: response times are more lenient while this public health emergency is ongoing but recommend setting a benchmark to respond and report, e.g. 5 business days
  - You will also want to make sure whoever answers this call or email has gathered the appropriate information so that an Adverse Event can be reported
  - Record keeping is very important and you will want to ensure that you can keep a record of all information gathered from the Adverse Event report – even if you do not ultimately report the suspected Adverse Event
  - **Keep a detailed record of all calls and emails you receive about suspected or actual Adverse Events for 10 years per the statute**
- For more information, please review the FAQs on the FDA website here:  
<https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers>