



Proposed Amend Rule 1405 – Facility Survey Form

Section A – Facility Contact Information

A1. Facility name	
A2. FDA registration or FEI number	
A3. FDA establishment type	
A4. Warehouse address	
A5. Mailing address	
A6. Warehouse contact name	
A7. Contact title	
A8. Contact phone number	
A9. Contact email address	

Section B – General Operations

B1. # of employees at facility	
B2. # of buildings and square footage	
B3. Daily hours of operation	
B4. Weekly operating schedule	
B5. Does facility meet the definition of a “small business”?	<input type="checkbox"/> YES, facility has 10 or fewer employees and \$500,000 or less in total gross annual receipts <input type="checkbox"/> NO
B6. Does facility receive products sterilized with ethylene oxide (EtO)?	<input type="checkbox"/> YES <input type="checkbox"/> UNKNOWN, I do not know <input type="checkbox"/> NO (if NO, skip to Section G)

Section C – Warehouse Operations

C1. Please identify all methods of sterilization used on products received at your warehouse:	<input type="checkbox"/> Ethylene oxide (EtO/EO)	<input type="checkbox"/> Heat (moist or dry)
	<input type="checkbox"/> X-Ray	<input type="checkbox"/> Gamma radiation
	<input type="checkbox"/> Vaporized hydrogen peroxide (VHP)	<input type="checkbox"/> Electron beam (E-beam)
	<input type="checkbox"/> Other(s):	<input type="checkbox"/> Unknown
C2. For products sterilized with EtO, how long after aeration do these products arrive at your warehouse?	<input type="checkbox"/> Less than 1 day	<input type="checkbox"/> Between 1-7 days
	<input type="checkbox"/> More than 7 days	<input type="checkbox"/> Unknown
C3. Estimate how much of your warehouse square footage is used to store products sterilized with EtO:	<input type="checkbox"/> Between 0-25%	<input type="checkbox"/> Between 25-50%
	<input type="checkbox"/> Between 50-75%	<input type="checkbox"/> Between 75-100%
	<input type="checkbox"/> Unknown	
C4. Which best describes, on average, how often you receive products sterilized with EtO?	<input type="checkbox"/> Quarterly or Monthly	<input type="checkbox"/> Weekly
	<input type="checkbox"/> Daily	<input type="checkbox"/> Other:
C5. How are products sterilized with EtO received? (select all that apply)	<input type="checkbox"/> Individual packages via UPS/FedEx/USPS	<input type="checkbox"/> Open air trailer or truck
	<input type="checkbox"/> Bobtail/box truck	<input type="checkbox"/> Truck trailer
	<input type="checkbox"/> Shipping container	<input type="checkbox"/> Unknown



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C6. Which best describes, on average, how long products sterilized with EtO remain in your warehouse?	<input type="checkbox"/> 1-7 days	<input type="checkbox"/> 7-30 days
	<input type="checkbox"/> More than 30 days	<input type="checkbox"/> Unknown

Section D – EtO Procedures

D1. Does your warehouse have any special policies or procedures for handling products sterilized with EtO? (if NO, skip to section E)	<input type="checkbox"/> YES	<input type="checkbox"/> NO
D2. Does your warehouse identify incoming vehicles, packages, or pallets containing products sterilized with EtO?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
D3. Does your warehouse place products sterilized with EtO in designated rooms or areas of your warehouse?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
D4. Does your warehouse conduct any training, one-time or periodic, regarding handling of products sterilized with EtO?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
D5. Does your warehouse maintain any EtO-specific recordkeeping regarding products sterilized with EtO?	<input type="checkbox"/> YES	<input type="checkbox"/> NO

Section E – EtO Control Measures

E1. Please identify, if any, all equipment at your warehouse used for the capture and/or control of emission from products sterilized with EtO:	<input type="checkbox"/> None	<input type="checkbox"/> Fans/open windows
	<input type="checkbox"/> Tenting/strip curtains	<input type="checkbox"/> Fume hoods
	<input type="checkbox"/> Dedicated aeration rooms	<input type="checkbox"/> Aeration chambers
	<input type="checkbox"/> Filter media	<input type="checkbox"/> Dry bed scrubbers
	<input type="checkbox"/> Activated carbon beds	<input type="checkbox"/> Acid scrubbers
	<input type="checkbox"/> Oxidizer/abator	<input type="checkbox"/> Other:

Section F – EtO Monitoring

F1. Does your warehouse conduct any EtO monitoring?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
If YES, identify all methods of ongoing EtO monitoring in use:	<input type="checkbox"/> Handheld EtO detector	<input type="checkbox"/> Canisters/bags
	<input type="checkbox"/> Gas chromatography (GC) monitors	<input type="checkbox"/> Combustible gas monitors
	<input type="checkbox"/> Other:	
F2. In the past, has your warehouse or its agents or consultants conducted any sampling or analysis of warehouse EtO levels?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
F3. What are the highest EtO levels detected inside of your warehouse?	<input type="checkbox"/> No data	<input type="checkbox"/> Below 0.5 PPM
	<input type="checkbox"/> Between 0.5-5 PPM	<input type="checkbox"/> Greater than 5 PPM

Section G – Miscellaneous

G1. Please provide a copy of the following if available:	<input type="checkbox"/> Process flow diagram	<input type="checkbox"/> Floorplan
G2. Trade secret data claimed?*	<input type="checkbox"/> YES. List the questions with trade secret data (e.g. E1, F3): <input type="checkbox"/> NO	

*Under the California Public Records Act, documentation are presumably public records and may be disclosed to a third party except certain limited information are exempt from disclosure because it qualifies as a trade secret, as explained in the South Coast AQMD's Guidelines for Implementing the California Public Records Act. You must make such claim at the time of submittal to the South Coast AQMD. Check "Yes" if you claim that this form or its attachments contain trade secret information.