

FDA REGISTRATION CHECKLIST

Your step-by-step guide to FDA Food Facility Registration for the US Market.

Use this checklist to ensure your facility is prepared for successful FDA registration.



STAY COMPLIANT

Meet US FDA requirements.



AVOID DELAYS

Prevent import holds and shipment delays.



ACCESS THE US MARKET

Open doors to new business opportunities.



BUILD TRUST

Show US partners and customers you're compliant.



REDUCE RISK

Minimize recalls, penalties and enforcement actions.

1 FACILITY INFORMATION

- ☐ Legal business name is accurate and matches government records
- ☐ Facility address is complete and accurate
- ☐ Mailing address (if different from facility address)
- ☐ Primary business phone number
- ☐ Email address for FDA communications
- ☐ Name and title of the authorized official
- ☐ DUNS number (if applicable)
- ☐ Facility type (manufacturer, processor, packer, etc.)
- ☐ Product categories are identified correctly

2 US AGENT INFORMATION

- ☐ US Agent has a physical address in the United States
- ☐ US Agent is available during normal business hours
- ☐ US Agent agrees to act on your behalf with the FDA
- ☐ US Agent information is included in registration
- ☐ US Agent consent form is on file (recommended)

3 FDA REGISTRATION DETAILS

- ☐ Create or log in to your FDA Industry Systems account
- ☐ Complete the Food Facility Registration (FFR)
- ☐ Select the correct facility location
- ☐ Identify the correct product categories
- ☐ Review all information for accuracy
- ☐ Submit registration
- ☐ Save confirmation number and registration certificate
- ☐ Verify registration status is "Active"

4 POST-REGISTRATION REQUIREMENTS

- ☐ Renew registration during each renewal period (Oct 1 – Dec 31)
- ☐ Update registration if any information changes
- ☐ Maintain a valid US Agent at all times
- ☐ Ensure FSVP compliance with your US importer
- ☐ Respond promptly to any FDA communications

IMPORTANT REMINDERS



FDA registration must be renewed every 2 years between Oct 1 – Dec 31.



Registration does not guarantee FDA approval of your products.



Your products may be subject to FSVP, Prior Notice and other import requirements.



A valid US Agent is required for foreign food facilities.



Keep your registration information up to date.



Non-compliance can result in shipment delays, refusals or enforcement actions.



NEED HELP WITH FDA REGISTRATION?

ClearPath Compliance Co. makes FDA registration simple, accurate and stress-free.



EXPERT GUIDANCE
from compliance professionals



ACCURATE & COMPLETE
registrations done right the first time



ONGOING SUPPORT
renewals, updates and FDA inquiries



FOCUS ON YOUR BUSINESS
we'll handle the compliance

LET'S GET YOU US MARKET READY.



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