+1 (210) 956 - 1505
+1 (412) 606 - 4399
400 E. Randolph Street Ste: 715-C
Chicago, IL 60601 U.S.A

New FDA Guidance: What It Means for OAI Facilities

Post-Warning Letter Meetings Under GDUFA

The FDA has finalized its **"Post-Warning Letter Meetings Under GDUFA"** guidance, turning a GDUFA III commitment into a formal process. This gives facilities with an **Official Action Indicated (OAI)** status a chance to meet with the FDA and review their **CAPA plan** before reinspection—potentially speeding up the return to compliance.

Finalized: June 2025
Key Update: Locked-in timelines, eligibility rules, and decision goals

Who's Affected?

This guidance applies to facilities that:

- Hold an **FDA Establishment Identifier (FEI)** for human generic drugs (API or finished dosage).
- Are under **OAI status** due to cGMP violations and received a **warning letter**.
- Are covered by **GDUFA III** (paid the current-year fee or listed in a pending ANDA).
- Have warning letters citing **section 501 violations** (human-drug related).

Each FEI is treated independently. Only the facility, its parent company, or an authorized legal rep can request a meeting.

Performance Goals & Timelines

The FDA aims to respond to meeting requests within 30 days:

- **50%** in FY 2024
- **70%** in FY 2025
- **80%** in FY 2026–27

Meetings typically occur **~6 months** after the warning-letter response, but earlier dates are possible.

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Are You Eligible?

You can request a meeting if:

- Your facility is under **OAI** status.
- You've paid the **GDUFA fee** or are in a pending ANDA.
- The warning letter cites **human-drug CGMP violations**.

Each FEI gets **two chances** per warning letter. If the first is denied, wait **3 months** before trying again.

How to Request a Meeting

- **Who:** Only the facility, parent company, or legal rep
- **Where:** Email to FDA-GDUFAIII-PostWarningLetterandReinspectionRequests@fda.hhs.gov
- **When:** After the 15-day warning-letter response window closes

What to Include in Your Meeting Package

- Facility details (name, FEI, warning letter #, fee status)
- Preferred dates, format (video/tele/face-to-face), and a 1-hour agenda
- **CAPA summary table** with root causes, owners, timelines, and progress
- Key questions for FDA about CAPA adequacy
- The FDA wants **evidence of progress**, not just promises.

Inside the One-Hour Meeting

- FDA chairs and sets the pace
- 10-minute facility presentation
- 30+ minutes of Q&A on CAPA progress
- Clear action items before closing

You can take your own minutes—FDA won't sign off on them.

Action Steps We Recommend

1. **Respond first.** Submit a strong warning-letter response before requesting a meeting.
2. **Track everything.** Use a dashboard to monitor CAPA progress.
3. **Time it right.** Aim to request around Month 4 post-warning letter.
4. **Show, don't tell.** Include real evidence—batch records, photos, logs.
5. **Mock review.** Vet your package internally or with consultants.
6. **Rehearse.** Prepare a 10-minute deck and practice Q&A.
7. **Plan for both outcomes.** Be ready for either a meeting or inspection.
8. **Keep FDA updated.** Send periodic updates to show engagement.

Need Help?

Our team of SMEs and former FDA investigators and compliance experts can:

- Review your CAPA plan
- Strengthen your evidence
- Coach your presenters

Contact us to get started.