

Inspection Items to Consider (electronic desk file on the Mail Log)

BACKGROUND:

During the pre-inspection portion of the inspection process, Specialists notify Reviewers to ask if there is anything they would recommend be observed or audited during the inspection (see **ICSOP0012, Pre-Inspection Activities**, Section 6). Many times there are documents and situations that could be reviewed during an on-site inspection but by the time the inspection is scheduled, these issues are forgotten.

The Mail Log can provide a way to track and keep communication open between Policy, Evaluation and Licensing (PEL) and Inspection and Compliance (IC) regarding items to consider during the on-site inspection. It can serve as a “desk file” or tickler list for issue to review during the inspection

HOW TO TAG a Mail Log (ML) item with “Inspection Item to Consider”

1. This can be done during any step in the ML process, whether it is active or complete.
 - a. Create
 - b. During review
 - c. Finalization
 - d. Notification
2. It can be done by either the Reviewer or the Specialist

Example - if the Specialist receives a Notification for a specific ML from PEL and would like to place it in their “Desk File,” they can tag the ML item.

- i. Open ML item
- ii. Click on “Edit Mail Item# xxxxxx”
- iii. Add Tag “Inspection Item to Consider” and click on +Add
- iv. Click on Update to save the tag

Submission Classification

Submission Subtypes + Add

- Residue Clearance ✖
- Safety-Field ✖
- Safety-overdose ✖
- Safety-specialized claim ✖

Agents + Add

- Classical Swine Fever Virus ✖

Synopsis of Reviewer Response
Safety studies demonstrate safe for use in pregnant animals, and 21 day withdrawal for IM administration. Additional field safety required for NEPA.

Tags + Add

- Regulatory Flexibility ✖
- Paperless ✖

Licensing Plans

ID	Est	Product Code	Count in Active Time to Licensure
			Y

+ Licensing Plan

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This Tag does not require the item to be inspected during the on-site inspection, but may be a part of the pre-inspection process to prepare for the inspection. Also, this does not child loop or move the document forward, it only tags the document for review during the pre-inspection process.

HOW TO CREATE “desk file” REPORT for pre-inspection review

1. Go to Mail
2. Searching
3. Master Search
4. Enter
 - Establishment
 - Date Submitted From (date of last inspection) To: (current date)
 - Tag: Inspection Item to Consider
5. Click on Search
6. Click on Excel spreadsheet and customize as needed

If there are questions as to why an item is tagged, please consult with the document author during the pre-inspection review.