Form Number	
Date of Form	
Completed by	
Program	OHAFO Human Food, OHAFO Animal Food, OHAFO Egg Safety Rule, OMDRHO Medical Device
Division	HAFE1; HAFE2; HAFE3; HAFE4; HAFE5; HAFE6; HAFW1; HAFW2; HAFW3; HAFW4; HAFW5; HAFW6
State Agency	
State Phase	Phase I, Phase II, Phase III, Joint Inspection
Review Date	
Inspection Start Date	
Firm Name	
FEI Number	

This Checklist is used for:

☐Quality Factor Check (Quality Control) (ORA use only)

☐Audit (Quality Assurance - After Product is Released) (ORA use only)

☐Training Purposes

☐Self-Evaluation/Job Aid

☐State Review (State use only)

Tab 1- Form Information

When completed- sign off on the form using your e-signature for QMiS. For help to reset your e-signature. See "How to Reset Your E-Signature" in QMiS. (WI-000171)

If you need to add others to review this checklist- use modify step during sign-off and place the form in-process. See "How to Modify a Step in QMiS" in QMiS. (WI-000400)

If you are not done with the form - save it - and sign off as in-process for later.

Link to the IOM

Link to the RPM

Tab 2- Quality Factors

Quality Factors	Yes	No	N/A	Comments
1. Inspection information is entered in the eSAF system or other FDA-approved systems. (SOW)	☐	☐	☐	
2. The record in eSAF (or other FDA-approved systems) contains accurate and complete information. For example: legal firm name, operation status, PAC code(s), etc. (IOM 5.11.4)	☐	☐	☐	
3. The information contained in the narrative report holds the level of detail negotiated between the FDA division and the state agency. (Human Food SOW)	☐	☐	☐	
4. The report and record in eSAF (or other FDA-approved systems) are factual, objective, and free of opinions. (IOM 5.11.4)	☐	☐	☐	
5. Appropriate FDA forms (such as FDA 3501, FDA 2481, VFD Tool, etc.) are utilized for inspection reporting per the SOW or as directed by the FDA division. (SOW)	☐	☐	☐	
6. All FDA or equivalent state forms associated with the inspection are legible, correct, and complete. Forms are properly executed and signed. (IOM 4.2.5; IOM 5.1.1, 5.2.2, 5.2.3)	☐	☐	☐	
7. If applicable and required by the SOW, the Form FDA 483 includes the following statements as a header above the 483 cites: “The observations noted in the form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.” (Medical Device SOW)	☐	☐	☐	
8. All exhibits (including labels and labeling) and/or attachments are identified per method mutually agreed upon with the FDA division. (IOM 5.3.8.2, 5.11.5)	☐	☐	☐	
9. If applicable, the inspection was pre-announced to firm management following the instructions set forth in the applicable SOW or as directed by the FDA division. (Medical Device SOW, Inspection of Egg Farms-CP 7303.836)	☐	☐	☐	
10. If applicable, appropriate guidance documents and/or required handouts (per the applicable SOW or as directed by the FDA division) are provided to the firm. (SOW)	☐	☐	☐	
11. FDA regulated activities performed by the inspected facility are fully documented in the narrative report to allow for a	☐	☐	☐	

Quality Factors	Yes	No	N/A	Comments
correct determination of the firm's workload obligation status by the FDA. (Animal Food SOW)				
12. The narrative report establishes clear FDA jurisdiction and interstate commerce. (IOM 5.11.4.3.5, 5.11.4.3.6)	☐	☐	☐	
13. If applicable, the report (for an inspection at egg laying farm, for example) details adherence to proper biosecurity procedures. (Egg SOW, Inspection of Egg Farms-CP 7303.836)	☐	☐	☐	
14. Full names and titles of owners, partners, and/or corporate officers and their responsibilities and authorities are detailed in the narrative report. If required, supporting documentation is included. (IOM 5.3.6.1, 5.11.4.3.7)	☐	☐	☐	
15. The report contains the name, title, and address (i.e. physical mailing and e-mail) of top management official to whom FDA correspondence should be addressed. (IOM 5.11.4.3.3, 5.11.4.3.4)	☐	☐	☐	
16. Applicable registration(s) are detailed in the report, including current status. (SOW)	☐	☐	☐	
17. When microbiologically oriented inspections are conducted (e.g. environmental sampling inspections), a more detailed description of the manufacturing process and possible routes of contamination are detailed in the narrative report. (Human Food SOW)	☐	☐	☐	
18. If applicable, follow-up on previous objectionable conditions noted on FDA 483 (or equivalent state form) or any state or agency actions are explained in the report. Explanation includes what measures the firm took to correct the condition(s). (SOW)	☐	☐	☐	
19. The report and FDA 483 (or equivalent form) detail the conditions found with sufficient narrative and evidence to enable an FDA assessment of the significance of any objectionable conditions or practices. (Human Food SOW, Medical Device SOW, IOM 5.11.4.3.13.1)	☐	☐	☐	
20. The inspection report contains an appropriate level of detail to ascertain management's response and/or actions taken or promised. (Human Food SOW, Egg SOW, Medical Device SOW)	☐	☐	☐	
21. Regulatory refusals are clearly stated in the report (name of person who made refusal and if available, the reason why the refusal was given). (IOM 5.11.4.3.14)	☐	☐	☐	
22. The report contains a summary of follow-up to open FDA consumer complaints and/or corrective actions taken due	☐	☐	☐	

Quality Factors	Yes	No	N/A	Comments
to an FDA recall, if required per the applicable SOW or directed by the FDA division. (Human Food SOW, Animal Food SOW, IOM 5.11.4.3.11)				
23. If applicable, samples collected during contract inspection (including state regulatory samples) provide an appropriate level of detail to support FDA regulatory actions. (IOM 5.11.4.3.17)	☐	☐	☐	
24. For samples collected under the contract, information is entered in eLEXNET, and/or any other approved system for reporting results. (SOW)	☐	☐	☐	
25. Other.	☐	☐	☐	

Tab 3- Final Comments-Attachments-Links

Final Comments or Issues

Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
00	I	07/02/2019	Kathleen Close HAFW2 State Liaison	Joann Givens, OHAFO-W Program Director, Vinetta Howard-King, OHAFO-E Program Director
01	R	09/09/2020	Kumudini Carter, OHAFO-W Program Quality System Manager	Glenn Bass, Acting OHAFO-W Program Director, Vinetta Howard-King, OHAFO-E Program Director
02	R	See Header Above	Kumudini Carter, OHAFO-W Program Quality System Manager	Scott MacIntire, Acting OHAFO-W Program Director, Vinetta Howard-King, OHAFO-E Program Director

* - D: Draft, I: Initial, R: Revision

Change History

Revision #	Change
00	New Procedure
01	Changed the header of the document. Added when ORA and when State can use the checklist. Change Tab 1 to the most updated version. Minor word edits in questions 11 and 20.
02	Added State Phase Tab 1: Added new work instruction to How to Modify a Step in QMiS. Removed Other in checklist selection Minor typo corrections Question 18: added “any” and “or agency” Made form fillable