U.S. FOOD & DRUG ADMINISTRATION

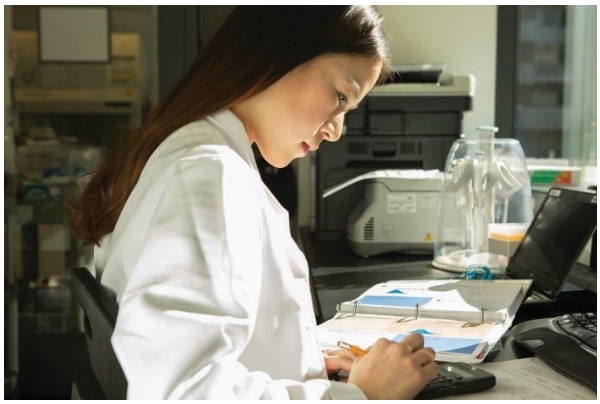
FDA FACT SHEET

Remote Regulatory Assessments of Animal Food Facilities – Veterinary Feed Directive (VFD) Pilot Study

The U.S. Food and Drug Administration (FDA) is introducing a new pilot study for selected animal food facilities to VOLUNTARILY opt in to have the agency conduct Remote Regulatory Assessments (RRA) of their Veterinary Feed Directive (VFD) records. The data from this voluntary pilot study can benefit both the animal food industry and FDA by helping reduce on-site inspection time, to keep FDA and facility personnel safe during the COVID-19 pandemic, and in the future to more efficiently use on-site inspection time. FDA's overall RRA pilot study was created to explore alternate ways to protect the public and provide regulatory oversight during the COVID-19 pandemic beyond traditional on-site inspections.

Key facts about RRA for an animal food facility

- RRAs are strictly VOLUNTARY for animal food facilities.
- FDA will reach out to selected individual facilities to request their voluntary participation.
- There is no penalty for opting out of the RRA. Facilities can decline to participate at any time.
- Animal Food RRAs help the FDA assess a facility's compliance with requirements under the Federal Food, Drug, and Cosmetic (FD&C) Act and animal food safety regulations.
- The RRA includes a review of facilities' records and an interview (call or video-stream) with a facility about their records.
- Any issues will be discussed with management at the close-out meeting.
- If concerns are found with the records, FDA will discuss those concerns with the facility, which gives them time to correct concerns prior to any future inspection.



What are the benefits of an RRA?

- For animal food facilities:
  - Potentially decreases future on-site inspectional time in a facility, because a portion of the record review will already have been completed.
  - Assesses facilities' compliance with certain regulations by FDA outside of an inspection, which could allow facilities to make corrective actions prior to their next FDA inspection.
- For FDA:
  - Helps FDA continue to provide oversight of the animal food industry while protecting both the industry and FDA staff during the COVID-19 pandemic by limiting in-person contact.
  - Initial reviews of the RRA pilot study may be used to develop a future program that would allow use of RRAs as part of future inspection procedures. This may be a more efficient use of resources because it may reduce FDA on-site inspection time.

Is an RRA considered an inspection?

- No – RRAs are not considered FDA inspections under the FD&C Act.
  - No FDA 482: Notice of Inspection will be issued.
  - No FDA 483: Inspectional Observations will be issued.
  - A facility that does not wish to voluntary participate can opt out without penalty.

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What can an animal food facility expect during an RRA?

- A letter, sent via email, will be provided to the facility requesting voluntary participation in RRA.
- If a facility voluntarily agrees to participate, the facility will select a designee to work with the FDA staff to provide the requested information.
- The FDA staff will set up a meeting with the designee to explain the process.
- Information, including a facility's Veterinary Feed Directive (VFD) records, will be shared electronically and securely.
- The FDA staff will review information in a facility's records that will help them assess current compliance with applicable regulatory requirements; the FDA staff will also interview (call or video stream) the facility if necessary, to get clarification about the records.
- If a facility wants to provide context about the records provided to the agency, FDA is willing to meet with the facility (call or video stream) upon receipt of the facility's records.
- FDA staff and the facility's most responsible person or designee will hold a close-out meeting to verbally explain any concerns.
- RRAs do not result in an Establishment Inspection Report (EIR) or 483; written documentation will not be provided to the facility during the close-out meeting.

What types of records will be reviewed during an animal food RRA?

- FDA's initial RRA for animal food will focus on compliance with requirements under the VFD regulations.
- FDA is focusing on VFD records for the initial animal food RRAs because facilities subject to VFD are required to keep specific records that can be reviewed outside of an on-site inspection to assess a facility's general compliance with VFD requirements.

- The specific records requested for review will be communicated to the animal food facility once the facility has voluntarily agreed to participate in the RRA.
- FDA will evaluate the success of the initial VFD RRA and determine whether to expand the pilot study to other FDA animal food safety regulations.

Is FDA conducting RRA for other FDA-regulated products?

- Yes – FDA has also created RRA for human food and other FDA-regulated products.
- This fact sheet was designed specifically to provide information on the RRA VFD pilot study for animal food.

Whom can I contact if I have questions about the RRA process?

- If you have any questions after being invited to participate, please reach out to the FDA point of contact listed in the letter you received.

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