Report Type: 1005 – Mandatory Report (Initial)

EXPLANATORY NOTES:

Inferred or Computer-Generated Data that do not need to be asked of the respondent but that are "required":

- **Date of report**: Computer-generated **[13/13056]**
- **Type of submission**: Inferred from the qualifying questions (initial vs. follow up) **[75/19904]**
- **Unique report identifier** (ICSR #) **[N54/9269]** – This is the unique number the reporter will get for his/her report and will be used in all other reports. Several ICSR numbers will be linked to one reportable food event.

Color Key:

Black Font for question stem and responses (**red asterisk** = mandatory question)
Red font (no highlighting) is instructional/explanatory notes (how something might work)
Red font with highlighting are questions/issues for which we are awaiting responses from the FDA

Definitions:

The issue of online help/reporter help is under discussion. For the mandatory 1005 report, the reporter should be familiar and have access to the following definitions prior to generating a report view. We believe the educational efforts underway by the FDA will also help provide these.

1005 Reportable Food means an article of food, including animal feed but not including infant formula, for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

Responsible Party = Reporter for a 1005 Mandatory Reportable Food Report = or a person that submits the registration under section 415(a) for a food facility that is required to register under section 415(a), at which such article of food is manufactured, processed, packed, or held = or the "person" who submits the registration number for a facility that manufactures, packs, processes or holds a human or animal food product.

Food/Feed Facility=The site for which the Responsible Party is submitting a report. This site may find out about the product problem on their own (self discovery) or may occur through notification by another site. This may or may not be the site at which the adulteration originated (Adulteration Origination Site). The Responsible Party and the Food/Feed Facility contact may be the same or may be different. For example, for a large food company, corporate headquarters may be the responsible party for reporting for one or more food facility locations.

Adulteration Origination Site=The adulteration source; the site at which the adulteration originated and the first link in the distribution chain.

The definitions for Food, Food Additive and Animal Feed all need further revision by the FDA. These are placeholders.

Food means (1) articles used for food or drink for man or other animals, (2) chewing gum, or (3) articles used for components of any such article (such as food or color additives

Food additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substances used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. This does not include a new animal drug.

Color additive means a material which

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) the term "color" including black, white, and intermediate grays.

Animal Feed means an article which is intended for use for food for animals other than man and which in intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal. **NOTE: THIS DEFINITION WILL NEED TO BE REVISED. Animal feed is food under 201 F**

To generate the correct report subviews:

Prior to final report generation, the reporter will be asked the following questions to ensure the appropriate report generation. These questions will come after the main intro questions for report generation.

The following questions will take about a minute to answer and will enable us to generate the correct set of questions for your reporting situation.

1. About which type of product are you reporting? **[product intended use data field]** **Ask 2 regardless of response**	❍ Human Food ❍ Animal Food ❍ Both ❍ Unknown	
Is the food or feed facility site for which you are reporting:		
2. The site in which you are located? **Ask 3 regardless of response**	❍ Yes ❍ No ; I am the responsible party but not located in the food facility ❍ No, I am the U.S. agent for the food facility	
3. The adulteration origination site? This should be asked for both initial and follow up as the reporter may have more info	❍ Yes (show 3b) ❍ No (show 3a) ❍ Don't know/not yet sure	
	3a. Do you know the name of the adulteration origination site (AOS)?	❍ Yes __(Name of AOS)____ ❍ No
	3b. Did you distribute some or all of the suspect products?	❍ Yes ❍ No, we did not distribute the food product in any way (If no, ask 3b1 below)
		3b1. Did you dispose completely of the any affected foods? ❍ Yes (show 3b2) ❍ No (show report as below) 3b2. Method of disposal (check all that apply) ❑ Destroyed ❑ Reconditioned ❑ Diverted to Animal Food ❑ Other ❑ Unknown If answers are unsatisfactory disposal, report will be generated per usual. We will continue to include downstream information even though this reporter is unlikely to complete it. If answers are satisfactory, the following message will be shown: **You are not required by law to submit a report. However, we appreciate your doing so to assist us in our investigation. Would you be willing to complete a report?** ❍ **Yes (generate report)** ❍ **No (termination message0**

The answers to these questions can generate several report subviews; a summary of all the subviews will be developed once the approach to 1005 reports has been finalized. The report view we have modeled is in blue font below and represents the "maximum data" view. .

- ***Q2: Responsible party and food facility are different; this is a U.S. Food Facility (no U.S. Agent)***
- ***Q3 and 3a: The food facility is not the AOS, but they do know the name of the AOS***
- ***Q3b through 3b2: They have distributed the product or they have not disposed of the product in a satisfactory fashion.***