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Use of Tracers in Animal Food, Type A Medicated Articles, and Medicated Feeds

Guidance for Industry

This guidance replaces Compliance Policy Guide Sec. 680.100 Tracers in Animal Feed.

Submit comments on this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All written comments should be identified with the Docket No. FDA-2021-D-1246.

For further information regarding this document, contact AskCVM@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at https://www.fda.gov/animal-veterinary, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or http://www.regulations.gov.

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Contains Nonbinding Recommendations

Use of Tracers in Animal Food, Type A Medicated Articles, and Medicated Feeds

Draft Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

FDA's Center for Veterinary Medicine (CVM) receives inquiries regarding the use of "tracers" in animal food, Type A medicated articles, and medicated feeds. Tracers are ingredients added to these products to identify a particular product. The purpose of this document is to provide guidance on the use of tracers in animal food, Type A medicated articles, and medicated feeds. This guidance replaces Compliance Policy Guide (CPG) Sec. 680.100 Tracers in Animal Feed.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

Manufacturers of animal food, Type A medicated articles, and medicated feeds use tracers to identify a particular product, to allow for determination of the presence of a particular ingredient, or for other purposes. Tracers are designed to be inert, harmless, and easily detectable.

A tracer may be added to an ingredient, such as a mineral premix or a Type A medicated article, that will be used to manufacture a finished animal food. The finished animal food can be tested for the presence of the tracer and hence, the presence of the ingredient. For example, the manufacturer of a Type A medicated article may add a tracer to allow confirmation of the presence of that manufacturer's Type A medicated article in a Type B or Type C medicated feed, helping to discourage counterfeiting. The manufacturer of a mineral premix may add a tracer to allow another animal food manufacturer using that premix to ensure the correct ingredient was used in the food and is present at the appropriate inclusion rate. Animal food manufacturers may also use tracers to ensure that their manufacturing processes are adequate and under control. In these cases, a tracer would be used intermittently to assess the adequacy of the manufacturing process and would not be present in all products.

Some types of tracers may require specific analyses to be detected, while other types of tracers may be detected by visual inspection. For example, a tracer could be reduced iron particles combined with an approved color additive.

III. Policy – Animal Food

Substances intended for use as tracers in animal food are animal food products. If a tracer with the appropriate characteristics is used, measuring the amount of that tracer in an animal food can help a manufacturer make sure that an ingredient is present and uniformly mixed into that animal food.

Any substance/ingredient intentionally added to an animal food must be used in accordance with a food additive regulation (see 21 CFR part 573), unless it is generally recognized as safe (GRAS) among qualified experts for its intended use as described in 21 CFR 570.30, or it qualifies for an exemption from the definition of "food additive" in section 201(s) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)[1] (see section 409(a)(2) of the FD&C Act).

The Association of American Feed Control Officials (AAFCO) defines certain ingredients that are used as tracers in its Official Publication.[2] FDA does not intend to prioritize enforcement of applicable food additive requirements regarding the use of these ingredients published in the AAFCO Official Publication, provided there are no safety concerns about their use as tracers or their composition.

If you seek to use a tracer in animal food that is not included in AAFCO's Official Publication, it must be used in accordance with a food additive regulation, unless it is GRAS or otherwise exempt from the "food additive" definition (see section 409(a)(2) of the FD&C Act). FDA issues food additive regulations specifying the conditions under which an additive has been demonstrated to be safe and, therefore, may be lawfully used (see section 409(a)(2) of the FD&C Act and 21 CFR part 573). Section 409(b) through (g) of the FD&C Act provides for a petition process to establish that a use of a food additive is safe (see 21 CFR part 573).[3]

Like other animal food products, tracer products must comply with all applicable animal food label and labeling requirements. All ingredients in a tracer product, as required in 21

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[1] Under section 201(s) of the FD&C Act, the following types of substances are excluded from the food additive definition: (1) pesticide chemical residues in or on a raw agricultural commodity or processed food; (2) pesticide chemicals; (3) color additives; (4) substances used in accordance with a "prior sanction" (i.e., a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 under the FD&C Act, the Poultry Products Inspection Act, or the Meat Inspection Act); (5) new animal drugs; and (6) dietary ingredients in or intended for use in a dietary supplement (not applicable to animal food).

[2] The AAFCO Official Publication may be obtained at https://www.aafco.org/Publications.

[3] See CVM Guidance for Industry #221, "Recommendations for Preparation and Submission of Animal Food Additive Petitions" (June 2015) (https://www.fda.gov/media/86905/download).

CFR 501.4(a) except as permitted elsewhere, must be included in the ingredients list using their appropriate common or usual name and must be listed in descending order of predominance by weight.

When a color additive is used as a component of a tracer in animal food, the color additive must be listed in 21 CFR part 73, subpart A–Foods, or in 21 CFR part 74, subpart A–Foods, and be approved for the coloring of foods generally (see sections 721(a) and 402(a)(2)(A) of the FD&C Act). How color additives may be identified in the ingredients list of an animal food is specified in 21 CFR 501.22(k)(1) and (2).

Under 21 CFR 501.100(a)(3), incidental additives that are present in a food at insignificant levels and that do not have any technical or functional effect in that food are exempt from the requirement of a declaration on the label of their common or usual name. If the use of a tracer in animal food qualifies for the labeling exemption at 21 CFR 501.100(a)(3) for incidental additives, the tracer is exempt from the requirement that its presence be declared on the label of the finished food. In addition, there are uses of tracers where disclosing the presence of the tracer on product labeling would defeat its intended purpose, such as when a tracer is used for the detection of a counterfeit, or be impractical, such as when a tracer is used only intermittently to assess manufacturing controls. In these instances, FDA does not intend to prioritize enforcement of the applicable animal food labeling requirements (21 CFR 501.4) for tracer ingredients used in animal food products if these ingredients are defined as tracers in the AAFCO Official Publication.

IV. Policy – Type A Medicated Articles – Medicated Feed

Section 512 of the FD&C Act requires that the use of all ingredients in a new animal drug be approved via a new animal drug application or supplement. Therefore, a tracer may be used as an inactive ingredient in a Type A medicated article only if its use is approved via a new animal drug application (NADA), an abbreviated new animal drug application (ANADA), a conditionally approved new animal drug application (CNADA), a supplement to any of these applications, or permitted via a listing on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (Index listing).

As part of the pre-approval review of the (A)/(C)NADA, supplement, or Index listing for a Type A medicated article, FDA considers whether a proposed tracer can be used in the medicated article and whether it must be declared on the labels of the Type A medicated article and medicated feed manufactured from it. FDA will generally find that a tracer which has previously been accepted for use in animal foods can be used in a Type A medicated article. If FDA has previously not prioritized enforcement of the applicable animal food labeling requirements (21 CFR 501.4) for a tracer ingredient used in animal food products or has previously not prioritized enforcement of the applicable new animal drug labeling requirements for another Type A medicated article label (21 CFR 201.10), then FDA would generally not prioritize enforcement of the applicable new animal drug labeling requirements for a tracer ingredient used in a Type A medicated article.

Changes in the qualitative or quantitative formulation of an approved new animal drug,

including changes in the inactive ingredients, are considered major changes and must be submitted in a Prior Approval Supplement unless a regulation or guidance provides for a less burdensome notification of the change (see 21 CFR 514.8(b)(1)(iii)).[4] A holder of an approved application or Index listing for a Type A medicated article who wants to add a tracer must submit a Prior Approval Supplement (see 21 CFR 514.8(b)(2)(ii)(A)). If the tracer has previously been found acceptable for use in animal food, the holder may instead submit a Supplement – Changes Being Effected in 30 Days (see 21 CFR 514.8(b)(3)).

The following information should be provided in an (A)/(C)NADA, a supplement to an approved (A)/(C)NADA, or Index listing to support the addition of a tracer to a Type A medicated article:

- A full description of the tracer, including all of its components, using the appropriate common or usual name(s) or scientific data and information that identify each component;
- Specifications and test methods for the tracer;
- A batch formula, manufacturing instructions, and specifications for the Type A medicated article containing the tracer;
- Data to demonstrate that the tracer does not interfere with the assay of the drug in the Type A medicated article and the medicated feed;
- Stability data to support the requested expiry period of the Type A medicated article containing the tracer; and
- For a tracer that has not previously been accepted by FDA for use in animal food, any additional data that may be needed to demonstrate the tracer is safe for its intended use.

Measurement of the amount of tracer in a medicated feed manufactured from a Type A medicated article containing the tracer is not an acceptable substitute for the periodic drug assays required in 21 CFR 225.58, or any other drug assays, such as those used for medicated feed stability studies required in 21 CFR 514.1(b)(5)(x).

[4] See CVM Guidance for Industry #83, "Chemistry, Manufacturing and Controls Changes to Approved NADA/ANADA" (May 2007) (https://www.fda.gov/media/70323/download).