

## **Federal Register Notice, February 25, 2026 [Docket No. FDA-2026-N-0496]**

### **Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds**

Regarding whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.

The Agency is seeking to gather information on cGMP regulations for medicated feeds under 21 CFR parts 225 and 226. However, 21 CFR part 226 is for the current good manufacturing practice for Type A medicated articles, and a Type A medicated article is a new drug product as defined in 21 CFR part 510.3(g);

The term *new animal drug* means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed.

A Type A medicated article is not a medicated feed. A medicated feed is defined in 21 CFR part 558.3(b)(8);

A "medicated feed" means a Type B medicated feed as defined in paragraph (b)(3) of this section or a Type C medicated feed as defined in paragraph (b)(4) of this section.

In the Notice a Type A medicated article is defined as "an animal feed product containing a concentrated drug diluted with feed carrier substance." However, this is contradicted by the Agencies definition of a Type A medicated article under 21 CFR Part 558.3(b)(2) that states;

...It consists of a new animal drug(s), with or without carrier, with or without inactive ingredients.

The Agency's incorrect definition of a Type A medicated article's composition may have contributed to the incorrect inclusion of Type A medicated articles with their information gathering on the cGMP activities for medicated feeds. It should be noted that a Type A medicated article must be manufactured at a registered drug establishment per 21 CFR Part 207 and in accordance with section 510 of the FD&C Act. Should a facility manufacturing Type A medicated articles also manufacture Type B and/or Type C feeds form a Category II Type A medicated article it would also need to have a medicated feed mill license. But a facility that manufactures only Type A medicated articles should in no way be classified as a medicated feed mill. The Agency's proposal to combine all reporting associated with CGMPs for medicated feeds should therefore not have included the listings under 21 CFR part 226. As noted previously, these CGMPs do not apply to medicated feeds.