UNITED STATES FOOD & DRUG ADMINISTRATION

Medicated Feed Mill Licensing – 21 CFR Part 515

OMB Control No. 0910-0337

No Material or Non-Substantive Change to a Currently Approved Collection:

The Food and Drug Administration (FDA or we) is requesting a nonmaterial/non-substantive change to revise **Form FDA 3448**, Medicated Feed Mill License Application, currently approved under OMB control no. 0910-0337, "*Medicated Feed Mill Licensing*." Feed manufacturers that seek to manufacture a Type B or Type C medicated feed using Category II, Type A medicated articles, or manufacture certain liquid and free-choice feed using Category I, Type A medicated articles that must follow proprietary formulas or specifications, are required to obtain a facility license under section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b). Our regulations in part 515 (21 CFR part 515) establish the procedures associated with applying for a facility license. We require that a manufacturer seeking a facility license submit a completed medicated feed mill license application using **Form FDA 3448** in accordance with 21 CFR 515.10(b). We use the information submitted to establish that the applicant has made the certifications required by section 512 of the FD&C Act, to register the mill, and to schedule a preapproval inspection. **Form FDA 3448** may be accessed on our website at: https://www.fda.gov/media/70099/download. We are modifying the collection instrument to update the postal address, update the signature field, and include an email address for electronic submission. Specifically, we are removing the FDA mail code and room number from the postal address, as we no longer utilize these elements to effect internal distribution of the information. Instead, we are adding a dedicated email address to facilitate electronic submission of applications consistent with our regulations in 21 CFR part 11 (Electronic Records; Electronic Signatures), revised March 2, 2023 (88 FR 13018), by technical amendment to provide for electronic submissions, and in 21 CFR 515, revised June 21, 2024 (89 FR 51966) by technical amendment to update the postal address.-

While we have made no adjustment to our currently approved burden estimate, we believe these modifications will facilitate the submission of information to FDA by respondents.

Dated: June 2024