UNITED STATES FOOD & DRUG ADMINISTRATION-

OMB Control No. 0910-0191: Administrative Practices and Procedures;

Formal Hearings

**Request for Non-Substantive/Non-Material Change:**

Regulations in part 10 (21 CFR Part 10) govern practices and procedures for petitions, hearings and other administrative proceedings and activities conducted by the Food and Drug Administration (FDA, the Agency) under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Public Health Service Act, and other laws which the Commissioner of FDA administers. These provisions are currently approved under OMB control no. 0910-0191.

Section 562 of the FD&C Act (21 U.S.C. 360bbb-1) directs FDA to establish adequate dispute resolution (DR) procedures to ensure appropriate review of scientific controversies between FDA and members of regulated industry, including possible scientific advisory committee review. To implement this provision, we amended the general appeal regulation applicable across all FDA components (§ 10.75 (21 CFR 10.75), *Internal agency review of decisions*) to provide for advisory committee review (§ 10.75(b)(2)). At the same time and consistent with the mandates of section 562 of the FD&C Act, we adopted an approach whereby specific implementation procedures about scientific controversy associated with review of certain FDA decisions are detailed in center-issued guidance.

Disputes may involve complex judgments and issues that are scientifically or technologically important so it is critical to have procedures in place that will encourage open, prompt discussion of disputes and lead to their resolution. We have developed guidance that describes dispute procedures related to handling requests for decisions affecting animal drugs or other products for animals. To assist respondents in dispute resolution affecting animal drugs or other products that are regulated by Center for Veterinary Medicine (CVM), we have developed the guidance entitled, *“Guidance for Industry (GFI) #79, “Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine*”, (July 2005). Currently this information collection is approved under OMB control no. 0910-0566.

For efficiency of agency operations, we are requesting to consolidate the related information collection activity and account for burden we attribute to the recommendations found in the referenced guidance document in the information collection for 21 CFR Part 10 under OMB control number 0910-0191. Accordingly, we have adjusted the estimated burden to reflect an additional 4 responses and 40 hours annually to account for the burden of the dispute resolution guidance. Upon approval of this request, we intend to discontinue the collection of information currently approved under OMB control number 0910-0566.

**Submitted: September 2023**